STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE

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Dedicated

to

my Family,

friends

&

Teachers

ABBREVIATIONS

TUR	Transurethral resection
LS	Lichen sclerosis
UTI	Urinary tract infection
MRI	Magnetic resonance imaging
RGU	Retrograde urethrogram
VCUG	Voiding cystourethrography
BXO	Balanitis Xerotica obliterans
BMG	Buccal mucosal graft
QOL	Quality of life
IPSS	International prostate symptom score
MFR	Maximum flow rate
IIEF	International index of erectile function
SBP	Systolic blood pressure
T2DM	Type 2 Diabetes Mellitus
PVR	Postvoid Residual volume
VIU	Visual internal urethrotomy
USG	Ultrasonography
WHO	World Health Organization

ABSTRACT

Introduction: Urethral stricture is the narrowing of urethral lumen because of ischaemia of corpus spongiosum . The narrowing causes obstructive voiding dysfunction and irritative urinary symptoms which can lead to impaired renal function. Urethroplasty is considered to be the gold standard for management of urethral stricture. Of the various types of urethroplasty, buccal mucosal graft has most favourable outcome.

Aim of Study: To evaluate the outcome of buccal mucosal graft urethroplasty in patients with anterior urethral stricture.

Materials & Methods: A prospective study was conducted in the Department of Urology, Dayanand Medical College and Hospital, Ludhiana .Patients with anterior urethral stricture consenting to participate and fulfilling all the consensus criteria was included.

Results: Balanitis xerotica obliterans is the commonest cause of stricture. Meatal stenosis was present in 36% of the long anterior urethral stricture group. Buccal mucosal donor site heals with minimum complications. Medium length bulbar urethral strictures had 100% result at the end of follow up. Long urethral structure had a successful treatment in 15/22 patients (68%) satisfactory result in 4/22 patients (18%) and failure in patient who needed self urethral dilatation & perineal urethrostomy (13.6%)

Conclusion: Buccal mucosal graft has good graft properties for graft survival with minimal donor site morbidity.Dorsal onlay graft is the preferred form of graft placement. Buccal mucosal graft is an ideal substitute for urethra in treating medium length bulbar urethral stricture

Keywords: Buccal mucosal graft, Visual internal urethrotomy,IPSS, VCUG, RGU, , SBP.

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INTRODUCTION

The male urethra is divided into anterior urethra and posterior urethra. The anterior urethra includes penile urethra and bulbar urethra. The posterior urethra includes prostatic urethra and membranous urethra.

Corpus spongiosum surrounds the penile urethra. It lies in the ventral groove between the two corpora cavernosa. The tunica albuginea of the corpus cavernosa is thicker than that of corpora spongiosum. The urethra traverses the length of the penis within the corpora spongiosum. At its distal end the corpus spongiosum expands to form the glans penis, a broad cap of erectile tissue to cover the tips of corpora cavernosa. Immediately adjacent to the tunica albugineais bucks fascia which is the tough, elastic layer. On the superior aspect of the corpora cavernosa, deep dorsal vein, paired dorsal arteries & multiple branches of dorsal nerves are contained within the envelope of Buck's fascia. In the midline groove, on the lower aspect of corpora cavernosa, Buck's fascia splits to surround the corpora spongiosum. Consolidations of the fascia, lateral to the corpora spongiosum, attach it to the lateral surface of corpus cavernosa. Attached distally to the bottom of the glans penis at the corona, Buck's fascia extend into the perineum, enclosing each crus of the corpora cavernosa and bulb of the corpus spongiosum. It firmly fixes the structures to the pubis, ischium and inferior fascia of perineal membrane (urogenital diaphragm).

Anterior urethra extends from the inferior fascia of the urogenital diaphragm to the external meatus of the penis.

Fossa navicularis is contained within the spongy erectile tissue of glans penis which terminates at the junction of urethral epithelium with the skin of glans. This part of urethra is lined by stratified squamous epithelium.

The penile or pendular urethra lies distal to the investment of ischiocavernous musculature and is invested by the corpus spogiosum. The penile urethra is lined by simple squamous epithelium.

The bulbous urethra is covered by the midline fusion of the ischiocavernous musculature. It is invested by the bulbospogiosus and corpus spogiosum. It becomes larger and lies close to the dorsal aspect of corpus spogiosum, exiting at its dorsal aspect, before the posterior attachment of the bulbospongiosus to the perineal body. The bulbous urethra is lined by squamous epithelium which changes to transitional epithelium at the level of membranous urethra.[1]

HISTOLOGY

The wall of urethra is formed by three layers.

1. MUSCULAR COAT

The muscular coat of the prostatic and membranous urethra is the downward continuation of the detrusor muscle of the urinary bladder. It is innervated by the sympathetic nerve fibres. The striated muscle forms the sphincter urethra which surrounds the membranous urethra.[1]

2. MUCOSAL COAT

Proximally it is composed of transitional epithelium continuous with the bladder. This cell type terminates in the verumontanum, just distal to the opening of the ejaculatory ducts. Distally a mixture of stratified columnar epithelium and pseudostratified epithelium with mucous glands can be seen. The mucous membrane of the penile urethra is characterised by the frequent recesses associated with the tubular mucous glands of Littre, especially in the dorsal part of the urethra. Distally in the penile urethra, the mucosa becomes stratified squamous epithelium.[1]

3. **SUBMUCOSAL LAYER**

The sub mucosal layer extends throughout the length of urethra having rich vascular and erectile network.

ARTERIAL SYSTEM

The blood supply to the deep structures of the anterior urethra is derived from the common penile artery, which is the continuation of the internal pudendal artery after it gives off the perineal branch. From this point the

artery is termed the common penile artery and travels along the medial margin of the inferior pubic ramus. As it nears the urethral bulb, the artery divides into three terminal branches as follows:

The bulbar urethral artery which is a short artery or arteries of relatively large caliber that pierce Buck's fascia to enter the bulbospongiosus. These arteries are almost parallel to the path of the membranous urethra. The dorsal artery generally travels along the dorsum of the penis with deep dorsal vein medially and the dorsal nerves laterally with the coiled configuration. The artery uncoils as the penis elongates during erection, allowing flow to be maintained. Along its course, it gives off 3 to 10 circumflex branches (the circumflex cavernosal arteries) which accompany the circumflex veins around the lateral surface of the corpora cavernosa. Its terminal branches arborize in the glans penis. In many patients the branches pierce through the tunica and connect to the cavernosal arteries. The functional significance of these perforators differs from individual to individual. Proximally, the circumflex arteries are also part of the blood supply to the corpus spongiosum.

SUPERFICIAL PERINEAL SPACE

In males, superficial perineal space contains the continuation of corpora cavernosa, the proximal part of the corpus spongiosum and urethra along with the muscles associated with them, the branches of internal pudendal vessels and pudendal nerves.

The ischiocavernous muscle covers the crura of the corpora cavernosa. They attach to the inner surfaces of the ischium and the ischial tuberosities on each side and insert at the midline into Buck's fascia. Muscle surrounds the crura at their junction below the arcuate ligament of penis. The bulbospongiosus muscles are located in the midline of the perineum. They are attached posteriorly to the perineal body, to each other in the midline, as they encompass the bulbospongiosus and the crura of the corpora cavernosa at the base of penis.These muscles are

confluent with the ischiocavernous muscle laterally, and at their insertion at the Buck's fascia, covering the dorsal vessels and nerves at the base of penis.[1]

Urethral stricture is the common disease, which has affected mankind.[2] Urethral strictures are urethral lumen narrowing because of ischaemicspongiofibrosis.[3] The narrowing causes obstructive voiding dysfunction and irritative urinary symptoms which can ultimately impair renal function.[4]

Worldwide prevalence of urethral strictures is estimated to be 229-627/100,000.[5]

The etiology of urethral strictures is divided into four major groups: idiopathic, iatrogenic, inflammatoryand traumatic. Most common being idiopathic and iatrogenic (33% each) followed by traumatic causes (19%) and least beinginflammatory(15%).[5]

Iatrogenic causes include transurethral resection (41%), prolonged catheterization (36%), cystoscopy (12.7%), hypospadias repair (6.3%) and prostatectomy (3.2%).[5]

Trauma related urethral strictures are frequently due to straddle injuries compressing the bulbar urethra against the symphysis pubis. This pattern of injury is rarely associated with a pelvic fracture. Traumatic strictures tend to be short, with most of them less than four cm in length.[5]

Among inflammatory strictures, most commoncauses are urethritis (recurrent gonococcal urethritis), recurrent urinary tract infections (Escherichia coli),Lichensclerosis (LS). Inflammatory strictures only affect the anterior part and do not extend to cause posterior urethral strictures.[5]

Table showing age wise distribution of stricture etiology in India:[6]

Cause		Age : 40yrs or less	Age : 40yrs or greater	Value
Idiopathic		63	49	<0.05
Iatrogenic	Urethral Catheterization	19	39	not significant
	TUR	5	58	<0.05
	Cystoscopy	0	10	not significant
	Prostatectomy	0	7	<0.05
	Brachytherapy	0	7	<0.05
	Hypospadias Repair	22	2	<0.05
Inflammatory	Urethritis	20	21	not significant
Lichen Sclerosis		12	27	not significant
Traumatic	Perineal Trauma	4	5	not significant
	Pelvic Fracture	26	9	<0.05
	Penile Fracture	3	1	not significant
Total (404)		171	233	

Pathogenesis

Idiopathic etiology is the commonest among strictures. The pathogenesis for inflammatory stricture has been described by Chambers who reported that the first identifiable change in urethral stricture was the change in the

nature of the urethral epithelium from the pseudo stratified columnar epithelium to columnar epithelium that lacks the water proofing ability of the pseudo stratified variant. Consequently they hypothesized that the urine could extravaste and lead to fibrosis.[1]

Partial loss of urethral lining also predisposes to stricture formation. As it exposes the spongiosal vascular spaces to the passage of urine which results in superficial spongiothrombosis and further progresses to a layer of spongiofibrosis. The loss of any part of circumference of the epithelial lining generally results in narrowing of the lumen during healing. The residual epithelial margins are approximated by the natural urethral closure pressure so that unepithelialized defects form clefts that tend to heal by cross adhesion and epithelial over bridging. However intermittent passage of urine opens these clefts causing repeated separation and reexposure of the underlying vascular spongy tissue spaces - combined with relatively slow uroepithelial proliferation which leads to gradual increase in underlying spongiothrombosis and consequently spongiofibrosis and stricture formation.

Singh and Blandy explained association of inflammatory stricture disease with the midbulbar and distal penile segments of the urethra on the basis that most urethral glands were at these sites. Thus inflammatory strictures were the consequence of fibrosis starting initially in the corpus spongiosum, caused either directly from the extravasation of urine through the urethral epithelium or indirectly through the involvement of urethral glands at specific sites and subsequent extension into the spongiosum. Once started, fibrosis within the corpus spongiosum can cause constriction of the urethral lumen and with superaddedinfection, this can cause micro abscess formation within the urethral glands. This makes the fibrosis worse and may causeperi urethral extension of the fibrosis.[3]

Spongiofibrosis

The surgical importance of established urethral spongiofibrosis is its high predisposition to progress to stricture formation when it is inappropriately used in surgical repair. It is the overall extent of spongiofibrosis associated with a stricture and not only the length of stricture that properly determines both the type and extent of urethral repair required to achieve satisfactory long term resolution. If the longitudinal extent of urethral repair is limited to the length that is actually structured, as opposed to the length of spongiofibrotic abnormality, it usually results in re-stenosis.

Severe spongiofibrosis changes are often palpable and they are generally apparent urethrographically by a scarred reduction in the urethral lumen and excavation of the ducts of the glands of Litrre and Cowper. Endoscopically, spongiofibrotic urethra has a whitish colourquite distinct from the normal urethra which is pink because of the underlying vascular spongy tissue that is seen through the translucent covering of the urothelium. However, preoperative evaluation by sono urethrogram offers only a guideline – the critical extent of surgically significant spongiofibrotic gray urethral abnormality which may not be apparent until it can be accurately determined by the direct inspection at the time of operation when the urethra has been opened by an incision extending from truly normal pink urethra proximally and distally when it is revealed by a well defined thin layer of sub epithelial fibrosis that is clearly distinguishable.

With progressive constriction of the urethral lumen, if outlet obstruction develops secondary changes may arise in the lower urinary tract and even in the upper urinary tract. Theobstruction predisposes to recurrent urinary infection ;secondary prostatitis and even epididymitis. Upper urinary tract complications are less common now than they were half a century ago, but are still common in certain areas of world with less adequate access to urological care.

The results of dilatation and urethrotomy were recently reviewed by various authors, who concluded that urethrotomy had no advantage over

dilatation in terms of cure rate and if one urethrotomy or dilatation fails to cure a patient then a second rarely will and third never does.[7] Furthermore, the only strictures that regularly respond are single short strictures of the bulbar urethra and that also only in less than 60% of cases. Multiple strictures, stricture > I cm long and penile urethral strictures rarely respond. Various methods have been used to improve the results like: using laser to divide the stricture rather than cold knife, using stent to hold the stricture segment and the urethra open, or using self urethral dilatation to hold the urethra open after an initial urethrotomy.

The results of laser urethrotomy have no advantage over cold knife urethrotomy although theoretically the vaporization of the superficial annular intraluminal ring constriction may give better result but otherwise no added advantage.Intraurethral stents may be effective when spongiofibrosis is not too extensive. When stent is placed, the fibrotic tissues tends to grow through the stent into the lumen, particularly in traumatic strictures and those with periurethral fibrosis. Moreover, even when successful, there is significant morbidity with intraurethral stents because of urine pools causing post void dribbling and irritative symptoms. There is also pooling of semen after intercourse, interference with ejaculation and its perception. Some have discomfort at the site of stent. The option ofself urethral dilatation is not acceptableto many patients, who like to have their diseases treated by doctors rather than by themselves. Even those who are prepared to try self urethral dilatation tend to discontinue later because of difficulties. Thus the only treatment accepted by most of the patients with urethral stricture disease is urethroplasty.[7]

Banalitis Xerotica Obliterans

It is a form of lichen sclerosis. It was first described in 1928. It occurs up to 1 in 300 men. The cause is not clear. It commonly affects the glans penis and prepuce causing phimosis, with more extensive disease affecting the urethra as far back as the proximal bulbar urethra. The

treatment recommended is excision of the entire affected urethra and use of extra genital tissue (buccal mucosal graft) for reconstructionto prevent recurrent disease in the repaired area. These procedures have high failure rates up to 71%.

These patients present with weak stream, straining while passing urine, incomplete bladder emptying, post-void dribbling, urinary retention and recurrent urinary tract infections. On palpation, periurethralspongiofibrosismay be felt.[8]

Patient may even present with hematuria or pollakisuria which are likely to be the result of a stricture related complicationslike urinary stones, urethritis, prostatitis, epididymitis or infection of testicle.[9]

Combination of both RUG and VCUG provide a comprehensive image of the entire urethra and disclose valuable information about the number of strictures, stricture length, it's location and the remaining caliber of the narrowed urethra.

Ultrasonography is useful in the diagnostic work-up of urethral strictures as it measures stricture length more adequately and provides information about the surrounding spongiofibrosis.

Magnetic resonance imaging (MRI) is useful in the diagnosis of tumor related urethral stricture disease. CT voiding urethrography provides valuable information in case of stricture related fistulas.[9]

Uroflowmetry is useful in assessment of the urethral flow. A maximum flow (Qmax) of less than 15 mL per second raises the suspicion of lower urinary tract stricture. Urethral strictures typically produce a plateau at the level of Qmax.[5]

Urethroscopy/cystoscopy is a relatively easy and quick investigation that helps to determine the location of the stricture.[5]

Controversies in the management of urethral strictures

Stricture length:

Stricture length andit's location often determine the surgical technique.

Length is a main contributor towards failure but the type of repair may influence the success rate.[10] Han et al conducted study on 347 patients who had undergone various types of substitution urethroplasties and it was found that strictures longer than 6.5 cm were predictor of failure.[11] Stricture lengths longer than 3.9 cm located in the bulbar urethra were identified as a potential risk factor causing failure in oral mucosa substitution urethroplasty.[10] The length of a complex urethral stricture is not yet defined, due to the regional anatomical differences in the urethra. Various stricture lengths were identified as a risk for treatment failure. Mathur et al[12] and Eswara et al[13] identified 5.0 cm and 7.0 cm respectively as independent risk factors for urethroplasty failures.

Stricture length and treatment approach

Stricture lengths shorter than 2 cm

Stricture lengths shorter than 2 cm located in the bulbar urethra are amendable with the anastomotic urethroplasty. When strictures are located in the penile urethra, substitution urethroplasty is considered the appropriate approach.

Guralnick et al found in his study that anastomotic urethroplasty provides good results in bulbar urethral strictures shorter than 2 cm, in which the stricture is excised and both ends of the healthy urethra arespatulated and anastomosed.[14] Stricture length is controversial because it is uncertain which length of urethra can be excised without causing penile chordee when doing the AR. Although AR is reserved for stricture lengths shorter than 2 cm, Aghaji et al, reports a success rate of 88% in their group of ninety-eight patients where the length was 3 cm.[15] Eltahaway et al, published a study on largest series of 260 patients where 257 completed mean follow-up of fifty months. Their success rate was 99% for a mean stricture length of 1.9 cm.[16]

Stricture lengths between 2 cm and 4 cm

The best technique for above stricture length has not yet been determined. The options vary from augmented anastomotic urethroplasty

to dorsal or ventral buccal mucosa graft onlayurethroplasty in the bulbar urethra.

Augmented anastomotic urethroplasty combines the anastomotic urethroplasty with substitution graft for a bulbar stricture with dense fibrosis being 1 cm to 2 cm long. The segmental excision of the worst section of the stricture (only up to 2 cm) is followed by anastomosis spatulated over a BMG placed dorsal or ventral urethral wall (Holy et al).[17] A perineal incision is made and the urethra is circumferentially mobilised. The narrow segment is identified and at the distal end urethra is transected at that point. The 1 cm to 2 cm of the dense spongiofibrosis and urethra is excised. Aurethrotomy incision is made from this point through the entire extent of the stricture proximally to at least 1 cm of the healthy urethra. The proximal intrercrural space can be developed to help in taking tension off the anastomosis, if required. The urethra is anastomosed in the midline ventrally and sutured dorsally with 4-zero Vicryl in one layer to lateral margins of the quilted BMG.

Holy et al demonstrated that in dorsal and ventral BMG augmented anastomotic urethroplasty, the success rates varied between 82% and 97% at mean lengths varying from 2.8 cm to 4.9 cm. Follow-up varied between fifteen to thirty-six months.[17]

Stricture lengths longer than 4 cm

The literature agrees that strictures of this length can only be treated with substitution urethroplasty. If a bulbar stricture is longer than 4 cm, circumferential urethral reconstruction with a patch (BMG or flap) is preferred.[18] The buccal mucosa is an ideal graft because it is extremely resistant to infection.[19] Buccal mucosa retains its characteristics as a free graft and it’s tendency to contract is about 10% compared to the 50% of free skin grafts.[19] Another advantage of the use of BMG over genital skin, is the relatively less dissection that is required for urethroplasty, which avoids genital skin scarring.

Urethral strictures can lead to various complications like: recurrent UTI,

acute urinary retention, bladder diverticulum, urethrocutaneous fistula, bilateral vesicouretericreflux and unilateral vesicoureteric reflux.[5] Surgery related complications include: bleeding, infection, incontinence, impotence and stricture recurrence.

AIMS AND OBJECTIVES

- To evaluate the outcome of buccal mucosal graft urethroplasty in patients with anterior urethral stricture.

REVIEW OF LITERATURE

URETHROPLASTY

Many surgical techniques have been described and gradually refined. The exact choice of technique depends on various factors like: previous urethral treatments, number of strictures, stricture length, location, etiology, comorbidities, the quality of corpus spongiosum, surrounding tissues and potential graft sites.[9] Mostly urethroplasty is considered to be the gold standard for management of urethral stricture and stenosis. Various studies conducted for excisional urethroplasty and use of grafts show higher long-term success rates than any other form of stricture management.[20]

Wong et al conducted a study in 50 men with traumatic stricture of the posterior urethra following pelvic fracture injury in which he compared the outcome of urethrotomy and urethroplasty. In the first six months, men were more likely to require further surgery in the urethrotomy group than in the primary urethroplasty group (RR 3.39, 95% CI 1.62 to 7.07). After two years, 16 of 25 (64%) men initially treated by urethrotomy required continued self-dilatation or further surgery for stricture recurrence compared to 6 of 25 (24%) men treated by primary urethroplasty.[21]

Anastomotic urethroplasty involves stricture resection and end-to-end anastomosis. It is mostly done when the stricture is short (<2 cm) and is in the bulbar urethra, cause mainly being traumatic straddle-type injury.[5]

In substitution urethroplasty or graft urethroplasty, urethra is mobilized in the area of stricture, dissected from the corpora cavernosa and opened along the urethra for the entire length of the stricture. This can be done through ventral, dorsal or lateral approach. Following this, a skin graft is sutured to the defect to create a wider urethra.[5] Split and full thickness skin grafts can be taken from different sites like: scrotum, penis,

extragenital sites (ureter, saphenous vein, appendix, colon, medial upper arm, neck, lateral chest, abdomen, bladder mucosa) and more recently oral mucosa has also been used.[22]

Poor prognostic factors for urethroplastyare :Periurethral fibrosis, Poor vascular supply, Periurethralphlegmon, Poor tissue availability, Previous instrumentation, Long urethral stricture and Balanitis Xerotica Obliterans(BXO). In the presence of risk factors, staged urethroplasty is advocated.

Graft take occurs in two phases: imbibition and inoculation. It takes total 96 hours. During the initial phase of imbibition, the graft survives by drinking nutrients from the adjacent host bed and it losts up to 48 hours. During this phase the graft temperature is less than the body temperature. In response to the growth factors produced by the hypoxic vessels in the graft during inoculation, new vessels are produced as buds from arteries, veins and lymph channels in the vascular bed. These new vessels grow through the fibrin matrix that has formed between the graft and graft bed and penetrate the graft to hook up with the vessels in the sub dermal and intradermal plexus thus reperfusing the grafted material. During this stage the temperature of the grafted tissue rises to the core body temperature. The process of take depends both on the nature of grafted tissue and conditions of the host bed.

Anantkumaret al in his study has reviewed about the management of BXO via single stage or multiple stage procedures. They had complications of graft loss, glans cleft narrowing and stromal revision in 5 out of 14 of their staged urethroplasty patients. None of their 25 single stage urethroplasty patients had similar problems. Recurrent stricture was noted in 21.4 % of patients who had two stage procedure vs 12% of single stage urethroplasty patients.[7]

Jean V.Joseph et al reviewed their 38 staged urethroplasty patients. He concluded that stage two urethroplasty is often converted into multistage procedure. A single patient required three revisions for stage one procedure before he was fit for stage two procedures.[23]

Ezopalminteri et al concluded that stage two urethroplasty involves considerable patient inconvenience and increased risk of morbidity because of multiple anesthetic procedures.[24]

Revisions are common with staged urethroplasty and approximately 50% of patients who underwent two stage procedure were converted into three stage procedure. Penile urethroplasty is particularly susceptible to revision. It has a recurrence rate of 4% at follow up of 6 month in best of hands.[25]

Grafts are placed dorsally in case of anterior urethral stricture disease.

1. Graft is placed overcorporal bodies which provides good support, prevents sacculation and pouch formation.Good vascular bed potentiating grafts take.Good immobilization of the graft.Less chance of graft shrinkage and chordee.A potential for roof strip epithelial regeneration according to the principles of Dupley and Davis.[26]

2. Urethrocutaneuos fistula can be prevented by adequate duration of indwelling catheter.

3. It preserves residual blood supply of corpus spongiosum[27]

4. In case of bulbar urethra, it requires less extensive opening of spongy tissue as urethra is positioned dorsally.

Sherbuny et al conducted study in dogs using buccal mucosal graft urethroplasty and found that BMG shrinkage was less than 10%. As compared to full thickness skin graft and bladder mucosal graft, buccal

mucosal graft had less inflammation, less fibrosis and uniform graft thickness at 3 months after grafting.[28]

Oral mucosa grafts have various favorable properties as they are flexible, easy to harvest, trim and have an excellent microvasculature favorable for graft-taking. Due to its natural moist location, oral mucosal graft adapts easily in the urethral passage thus giving good long-term results.[29]

Lumen et al reviewed 18 papers for analyzing the efficacy of penile skin graft (PSG) vs buccal mucosal graft (BMG). In total, 428 and 483 patients were treated with PSG or BMG respectively. Follow-up duration was 64.1 versus 42.1 months ($p < 0.0001$) and stricture length 6.2 versus 4.6 cm ($p < 0.0001$) for PSG and BMG, respectively. Success of urethroplasty with PSG was 81.8% versus 85.9% with BMG ($p = 0.01$).[22]

Buccal Mucosal Graft

The uniqueness of buccal mucosa with its histologic and antibacterial properties make it superior tissue for reconstruction. The unique structure of the buccal mucosa allows it to be an excellent grafting material. It is 500 micrometer thick and is a nonkeratinized, stratified squamous epithelium consisting of four layers. The stratum basale or germinative layer of the epithelium rests against the basement membrane and provides the progenitor cells for cellular division. The basale is two or three cell thick and includes melanocytes, antigen presenting Langerghans cells, sensory Merkel cell and lymphocytes. It has rapid turn over rate of 25 days.

The stratum spinosum is the next layer, which provides intercellular bridges that gives buccal mucosa the prickle appearance in light microscopy. The outer two layers (stratum intermedium & superficial) are difficult to delineate from each other. These cells are unique in that they are more firmly attached to each other than other keratinized tissue & provide excellent barrier production.

Beneath the basement membrane lies the lamina propria which contains more collagen and elastic tissue. Elastin fibres are more numerous in the buccal mucosa than in other tissues allowing buccal mucosa to recoil after stretching. The lamina propria further provides long slender papillary invaginations into the epithelia and loose collagen fibres and loops of capillaries from which epithelium gets its blood supply. The web like reticular layer of the lamina propria holds together the vasculature and nerves of the buccal mucosa. Collagen, elastin and ground substance depend on fibroblasts that also reside in the area.

The line between the sub mucosa and lamina propria is difficult to delineate. The sub mucosa, which is firmly attached to the underlying buccinator muscle, is also rich in collagen and elastin in addition to minor salivary glands and sebaceous glands. A major salivary duct (Stenson's duct) from the parotid gland pierces the buccinator muscle opposite the upper second molar on both sides.

The arterial blood supply to the buccal mucosa originates from the fascial artery, the buccal artery, the posterior superior alveolar artery and inferior superior alveolar artery of the external carotid.

Buccal mucosa is an ideal substitute for urethra because it has epithelium rich in elastin, which makes it durable and easy to handle, has high amount of type 4 collagen content, helps in good graft take. Lamina propria is thin compared to the skin and bladder mucosa, which facilitates inoculation and neovascularisation.[27] It has pan laminar plexus – so it can be thinned provided sufficient amount of deep lamina is carried to preserve the physical characteristics.[30] It has high capillary density.[27] The graft carries a wet epithelial surface.[30] Thickness of BMG makes it easy to handle. It is better substitute in case of BXO.[31] Harvesting and application of BMG is easy. Large volume is available.[27] It heals without much pain. There is no visible scar or deformity. It is resistant to infection.

Graft contracture is less than 10 %.[32] Resistant to progression of skin diseases like BXO.[33] Donor site is reepethelialized within 2 weeks.

Buccal mucosal grafts are mainly used in two cases. Most commonly, for ventral-onlay buccal urethroplasty for bulbar stricture and less commonly to augment an inadequate urethral plate during first stage Johansonurethroplasty, usually for penile stricture. Buccal-augmented Johansonurethroplasty is found to be especially useful in patients with lichen sclerosis and strictures after childhood hypospadias repair.[34,35]

BMGS IN STAGED URETHROPLASTY

Indications for staged urethroplastyincludes complex stricture, lengthy or caused by BXO. While traditional scrotal skin inlay has been used for two stage procedures, as it provides a large quantity of easily accessible tissue. It has significant limitations which include hair bearing area, excoriation and hyperkeratosis and increased risk of diverticulum formation. So flaps and grafts from extra genital skin and penile skin were tried. The penile skin use is limited by the availability of tissue, if the patient has been circumcised. The extra genital skin graft results are poor in some reports and good in others.

Schreiter& Noll described use of meshed split or full thickness skin grafts for staged urethroplasty. But it leads to graft contraction and excessive growth of granulation tissue through the spaces of the mesh. Wessels and Mc Aninch in a review described no apparent benefit attributable to the use of flaps over grafts. Long term results were comparable in both the groups. But grafts require less dissection and shorter operating time. Buccal mucosa offers the advantage of being accustomed to a wet environment, hairless, easy to harvest, resilient to infection, easy to handle thick epithelium and reduced likelihood of pseudo-diverticulum formation even when used ventrally, unlike skin inlay grafts, but it has a thin lamina propria allowing early inosculation. There are two published

series where buccal mucosa was used for two-stage urethroplasty in both the groups the graft performed well. About 23% of patients required minor revision after the first stage, with proximal graft stenosis comprising most of these revisions. One patient in each series developed an urethrocutanenous fistula and in contrast to two-staged repairs using skin grafts, none of the patients developed a diverticulum, although the follow-up was short. For circumferential repair of penile urethra two stage repairs using a free graft gives better results than a one stage repair using a flap.[36]

BMGS AS A VENTRAL/DORSAL FREE GRAFT

The use of a graft in urethral reconstruction has found renewed interest in the last two decades. Traditionally grafts have been placed on the ventral aspect of the urethra because it allows easier access to the urethra and better visualization of the stricture. Penile and nonhirsute extra genital skins have been used commonly for reconstructing the urethra. Using skin the common problems faced include those caused by contraction of the graft (especially with split-thickness grafts), and increased incidence of diverticulum formation and the risk of potential cosmetic deformity at the donor site. Penile skin has been used with long- term success rates of 50-95%. Ventrally placing a graft is likely to be associated with a higher rate of graft failure because of an inadequate graft bed and poor support, leading to diverticulum's formation, which then leads to post void dribbling and ejaculatory dysfunction. Previous experience using skin grafts for strictures in the penile urethra has not been encouraging, largely attributed to a less abundant corpus spongiosum than in the bulbar urethra, and a poorer blood supply and lower take rates. Barbagli et al., following the concept advocated by Monseur, introduced the dorsally placed graft, and postulated that dorsal placement is advantageous as it allows better mechanical support for the graft with a richer vascular bed for the graft from the underlying corporal bodies. While there are no randomized

controlled trails comparing ventral or dorsal placement of the graft using either skin or buccal mucosa, some authors report good long term stricture free outcomes in ventral on lay technique equivalent to dorsal on lay technique.[37] The overall success rate for a ventrally placed buccal mucosa graft is 85% at a mean follow-up of 36.9 months. This includes the entire population of strictures irrespective of the site. When bulbar strictures alone are considered the success rate is 89%. There were no reports of the development of urethrocutaneous fistula after a one-stage ventral BMG in the available series, but when skin was used, as a ventral graft fistula formation was common, especially where the graft failed to vascularize. In one of the largest published series, 21% of the patients reported some post void dribbling after surgery but no pseudo-diverticulum formation. The overall success rate with dorsally placed BMGs is 96% with a mean follow-up of 38 months. Dorsal on lay using skin gives success rates of 85% in comparison. None of these patients developed any urethrocutaneous fistulae or pseudo-diverticula.[38]

BUCCAL MUCOSA AS A TUBE GRAFT

Tubularized grafts fail largely because of inadequate graft take, as they are not circumferentially surrounded by vascularized tissue.[39] There are three published series where buccal mucosa has been used as tubularized graft. In all of these studies 37 of the 43 tubes constructed were to correct either hypospadias or epispadias. Urethrocutaneous fistula developed in 6 of 43 patients and there were 5 who developed meatal stenosis.[40] Recently Barbagli et al. described on one stage circumferential urethroplasty where, in complex cases, the diseased urethra is excised and replaced with buccal mucosa placed on a circumferential spongioplasty, thereby providing good fixation to a robust well vascularized underlying tissue. With a mean follow-up of 38 months none of the five patients developed a stricture. Therefore a tube graft using the spongioplasty technique may be more applicable to the bulbar

than the penile urethra. If there is inadequate surrounding spongy tissue, there will be inadequate graft take, which will inevitably lead to complications.

Sherbunyet al in their study in dogs found that buccal mucosal tube graft had success rate of 33% only even when the tube graft was surrounded by spongiosal tissue all around.[28]

COMPLICATIONS

Although serious complications resulting from harvesting a BMG are infrequent, until recently donor-site complications were not reported. Possible adverse effects of harvesting buccal mucosa include intraoperative hemorrhage, postoperative infection, pain, swelling, and damage to the parotid duct, limitation of oral opening and loss or altered sensation of the check or lower lip through nerve damage. Damage to the surrounding structures can be avoided by careful marking of the cheek mucosa before harvesting. It is recommended that the dissection should be at least 1 cm from the opening of the parotid duct. Harvesting mucosa from the cheek carries less morbidity than from the inside of the lips. Paraesthesia after harvesting a BMG is the commonest complication but is transient in most patients. Caldamone et al. reported two patients who developed scar contractures. Dubey et al. reported bleeding in one patient requiring surgical intervention, and in both these series both the check and lower lip were used for harvesting the graft.

Buccal mucosa has proved to be a useful alternative to skin. It is easy to harvest and to handle, is resilient to infections and accustomed to a wet environment. The BMG has been used successfully for treating all types of strictures, in which medium-term outcomes comparable to using skin as a substitute, but with less donor site morbidity and fewer complications. Because of its inherent advantages buccal mucosa has become the recommended source for tissue substitution during urethral reconstruction.

N.P. Gupta et al reviewed their experience in treating 12 patients with a long anterior urethral stricture. They reconstructed the anterior urethra using a one stage urethroplasty with a dorsal on lay buccal mucosal graft through a ventral sagittal urethrotomy. The urethra was approached via a small perineal incision irrespective of the site and length of the stricture. The penis was everted through the perineal wound. No urethral dissection was used on laterally or dorsally, so as not to jeopardize the blood supply. The mean (range) length of the stricture was 5 (3-16) cm and the follow-up 12 (10-16) months. They have used micturatingcystourethrogram at 21st post operative day, and in the presence of leak, they have retained the catheter for two more weeks for one patient.[41]

The results were good in 11 of the 12 patients. One patient developed a stricture at the proximal anastomotic site and required optical internal urethrotomy. Dorsal buccal mucosal graft urethroplasty via a minimal access perineal approach is a simple technique with a good surgical outcome. It does not require urethral dissection and mobilization and hence preserves the blood supply.

Anant Kumar et al have 39 patients undergone buccal mucosal urethroplasty for BXO related anterior urethral strictures. The 25 patients with a salvageable urethral plate (group 1) were treated with 1stage dorsal on lay urethroplasty using a cosmetic incision. The 14 patients with a severely scarred urethral plate, focally dense segments or active infection (group 2) underwent 2-stage urethroplasty. At a mean follow-up of 32.5 months (range 3 to 52) 3 patients (12%) in group 1 had recurrent stricture, of which 2 and 1 were treated with optical urethrotomy and urethral dilation, respectively. All patients had a normal slit-like meatus and none had chordee or erectile dysfunction. Four group 2 patients (28.6%) required stomal revision and 2 had glans cleft narrowing after stage 1 urethroplasty. Following stage two, 3 patients had recurrent stricture of whom 2 were treated with optical urethrotomy and 1 underwent repeat

urethroplasty. They have concluded that in BXO related strictures with a viable urethral plate one stage dorsal on lay buccal mucosal urethroplasty provides excellent intermediate term results. The cosmetic incision described provides a normal, wide caliber, slit-like glans. Two-stage procedures provide satisfactory outcomes but they are associated with a highest revision rate.[42]

Barbagli et alreviewed a total of 45 patients with an average age of 45 years underwent dorsal on lay skin graft urethroplasty between January 1994 and December 2000. Of the patients 23 had undergone an average of 2.6 prior endoscopic procedures (range 1 to 14). Preoperative evaluation include clinical history, physical examination, retrograde and voiding urethrography, and ultrasonography. In all patients the bulbar urethra was opened along its dorsal surface, the graft was sutured, splayed and quilted to the corpora cavernosa, and the urethra was rotated to cover the graft. In all patients penile skin was used as substitution material. Mean graft length was 4.7 cm (range 2.5 to 11). Three weeks after surgery voiding cystourethrography was performed. Average follow up was 71 months (range 41 to 110). Clinical outcome was considered a failure when postoperative instrumentation was needed, including dilation. Of 45 cases 33 (73%) were classified as successful and 12 (27%) were failures. The 12 failures were treated with internal urethrotomy (1), end-to-end-anastomosis (1), skin graft urethroplasty (2) and 2 stage urethroplasty (6). Six of the 12 initial failures had a satisfactory final outcome. The remaining 6 patients refused further surgical procedures and received a definitive perineal urethrostomy. They have concluded by saying that penile skin grafts used as a dorsal on lay for bulbar urethral reconstruction in a homogeneous series of patients showed a tendency to deteriorate with time. Longer follow up is required to compare penile skin with buccal mucosa as substitute materials for bulbar urethral reconstruction.[43]

Christopher J Kane et al have reviewed a retrospective analysis of patients who had undergone buccal on lay urethroplasty at 4 military medical treatment facilities participating in the Uniformed Services Urology Research Group. The database included demographic data, genito urinary history, preoperative symptoms (American Urological Association Symptoms score), Preoperative Urinary flow rate, stricture length and operative statistics. Postoperative follow-up data included symptoms score, flow rate, retrograde urethrogram results and complications. A total of 53 patients average age has 30 yrs (range 17-64) underwent buccal mucosal graft urethroplasty between January 1996 and March 1998 for refractory strictures.16 patients had undergone an average of 2.2 prior endoscopic procedures (range 1-7). Average stricture length was 3.6 + SD 1.8cm range 2 to 7.5 as measured on preoperative retrograde urethrogram. Follow-up averaged 25 months (range 11-40 months). Average symptom scores decreased from 21.2 (range 14-33) pre-operatively to 5.4 ranges (3-8) post operatively) (P.001). Average peak urinary flow rates increased from 7.9ml/second preoperatively to 30.1ml/ second post operatively (P0.001). Post operative retrograde urethrogram were available for 34 patients and were normal in 34. The overall complication rate was 5.4%. Three patients required endoscopic incisions. One patient has a recurrent narrowing and treatment is considered a failure. There were 4 sacculations (7.5%) and 6 narrowing, 3 of which required further treatment. Of the 53 patients 50 required no additional procedures (94.3%).[44]

Christopher E. Iselin et al has 29 men with a mean age of 43 years (range 10 to 81) who underwent dorsal on lay graft urethroplasty. Follow up included retrograde urethrogram at 3 weeks, 3 months and 12 to 18 months and thereafter when needed. Urinary flow was recorded as subjectively reported by the patients. The technique was used only for bulbar urethral strictures. A total of 23 patients (79%) had undergone

previous direct vision urethrotomy and/or open surgery. Dorsal on lay graft urethroplasty was used along in 12 patients (41%), and was performed with partial stricture excision and ventral strip anastomosis in 13 (45%). In another 4 patients (14%) the procedure was combined with an Orandi flap because the stricture extended significantly into the penile urethra. Penile skin graft was used in 27 patients (93%), whereas buccal mucosa was harvested in 2. Mean graft length was 6 cm. (range 3 to 9), and width ranged between 1.5 and 3 cm. Outcome was favourable in 28 patients (97%) for a median follow up of 19 months (range 10 to 37). One patient had symptomatic proximal stricture recurrence and 3 had radiographic evidence of caliber decrease of the repair but with no impact on urinary flow. They have concluded that dorsal on lay graft urethroplasty is a versatile procedure which may be combined with stricture excision and ventral strip anastomosis or an Orandi flap. Conceptually the technique offers the advantages of spread fixation of the graft on a fixed well vascularized surface, which may improve graft neo vascularization, reduce graft shrinkage and avoid sacculation. Buccal mucosa grafts used as a dorsal on lay for bulbar urethral reconstruction yield excellent results with minimal morbidity and low complication rates. Longer follow up will be required to confirm the durability of our results.[45]

Jack. B. Lewis et al reviewed the records of 78, 1-stage anterior urethroplasties performed via excision with primary anastomosis, buccal mucosal graft or penile fasciocutaneous skin flap techniques from September 1997 to December 2000 by a single surgeon (A. F.M.). All patients had more than 1 year of followup (range 1 to 4.5). Of the graft procedures only those in the bulbar urethra were included in analysis. Outpatient procedures were defined as those in which the patient was discharged to home within 24 hours. Clinical outcome was considered a failure when instrumentation was required postoperatively. Of the 78 anterior urethral repairs 54 (69%) were performed on an outpatient basis,

including 50 (93%) in which the outcome was successful compared with 21(88%) of the 24 inpatient procedures. Excision with primary anastomosis had the highest outpatient rate 28 of 31 patients (90%), followed by penile skin flaps 16 of 25 (64%) and buccal mucosal grafts (10 of 22 or 45%). Patient characteristics were significantly associated with outpatient procedures, including younger mean age (36 versus 46 years), shorter mean stricture length (3.1 versus 6.6 cm) and shorter mean operative time (3.2 versus 4.66 hours) (p 0.05). Anterior urethral reconstruction can often be completed safely and effectively on an outpatient basis.[46]

M.Bhandari et al have reviewed their experience in managing complex anterior urethral strictures with a dorsally / dorsolarterally placed penile / preputial vascularized flap, and to discuss the advantages of this procedure over a traditional ventrally placed flap. 40 patients (mean age 40.5 years) with recurrent strictures of the pendulous and / or bulbar urethra were treated with longitudinal penile / circum penile flap substitution urethroplasty. Nineteen patients underwent dorsal placement of the flap as an on lay (DO), whereas 21 patients had a ventral only (VO). Five patients needed inferior pubectomy to facilitate high proximal placement of the flap. Both groups had statistically similar ages, number of previous interventions, stricture site length and follow-up. After a median follow-up of 27.5 months, the stricture recurred in three (24%) of the VO and two (11%) of the DO groups (P>0.05). One patient in the VO group required surgical closure of the urethral fistula. Pseudo- diverticulum, sacculation with post void dribble occurred in six patients in the VO and none in the DO group (P=0.01). Dorsal placement of the pedicled flap is anatomically and functionally more appropriate than the traditional VO placement. DO preputial / penile flap urethroplasy is a versatile procedure and can be applied even for long anterior urethral strictures, including reconstruction of the meatus and high proximal bulbar strictures.[47]

Mundy et al have concluded that buccal mucosal free grafts appear to be satisfactory material for urethroplasty when applied as a patch. They are tough, resilient, easy to harvest and easy to handle, and leave no visible donor site. They appear to have no particular advantage over genital skin-free grafts or genital skin flaps in terms of cure of the stricture but avoid the cosmetic disadvantages of local genital skin. As it is not skin, buccal mucosa is resistant to skin diseases such as balanitis xerotica obliterans and is particularly resistant to infection. In short, buccal mucosa may not necessarily give more satisfactory results for the long-term cure of stricture disease; it has many characteristics to make it the material of choice for patch urethroplasty unless a free graft is contraindicated because of poor vascularity or active infection at the site of the stricture.[40]

George D Webster et al has reviewed their experience with 29 patients who underwent augmented roof top anastamoticurethroplasty. The stricture was in the bulbar urethra in all cases. Six patients had a completely obliterative stricture. Mean stricture length was 1.5 cm on retrograde urethrography and the mean excised length was 1.2 cm. In 9 of the 29 patients a roof strip anastomosis was augmented by a ventral on lay and in 20 a floor strip anastomosis was formed with a dorsal on lay. On lays included a pedicled skin flap in 7 cases and a graft in 22. Mean on lay length was 4.5 cm. At a mean follow up of 28 months (range 3 to 126) 27 of the 29 patients (93%) were stricture free and all those surveyed were satisfied with the procedure. Bergland et al reported on 18 patients with a mean stricture length of 15.1 cm reconstruction using the combination of a penile skin flap and buccal mucosal graft.[48]

Norman Dublin et al had 31 operations. Soon after surgery (that is first 48 h), 22 (73%) of the patients had little or no oral pain; 70% and 90% of the patients were able to eat and drink, respectively. 59% complained of numbness and 75% complained of tightness of the mouth. At discharge 6 days after surgery 90% of patients had little or no oral pain and all were

able to eat and drink, but 10% had moderate-to-severe oral pain, 39% had oral numbness, and 52% had tightness of the mouth. At the time of interview, 16% of patients had oral numbness (mess duration 13.6 months) and 32% had tightness of the mouth (mean duration 20.9 months) In answer to the question of whether they would have their cheek mucosa harvested again if required, 74% responded ‘yes’, 3% ‘no’ and 23% had mixed feelings. BMG harvesting is a good operation, as most patients were satisfied, but it is not without long-term complications and patients should be adequately informed.[49]

Pahwa et al conducted a study in which Asopa and Barbagli techniques of BMG urethroplasty were compared. Asopa technique was found to take lesser time to perform as compared to the Barbagli (142 versus 125 minutes. Cases where anterior urethra was found to be densely adhered to corpus cavernosum due to extensive spongiofibrosis, Asopa technique was found to be more suitable. The complication rate was found to be equal in both the approaches. In this series, 18 out of 20 patients were voiding satisfactorily at one-year follow-up in each group and postoperative imaging study in these patients showed a good lumen with no evidence of leak orextravasation. Hence no statistically significant difference was found in use of either of techniques.[50]

Barbagli et al showed that placement of buccal mucosa grafts into the ventral, dorsal or lateral surface of the bulbar urethra bear same success rates (83% to 85%) and the outcome was not affected by the surgical technique.[51]

Khwaja et al showed that for female urethral stricture reconstruction,dorsal buccal mucosal graft currently represents a prime choice. He performed dorsal buccal mucosal graft urethroplasty on 25 female patients aged 22 to 66 years and followed up them with lower urinary tract symptom, uroflowmetry and post-void residual urineassessments. Success rate was

found to be >90% with mean pre- versus postoperative Qmax being 5 ml/s versus 23.3 ml/s and mean residual urine being 178 ml versus18.5 ml.[52]

Krishna Nagalla conducted a restrospective study on 14 female patients and found that buccal mucosal graft urethroplasty is a feasible surgery for female urethral strictures with minimal short term complications. Mean preoperative maximum flow rate [Qmax] on uroflometry was 6.5 ml/second and the mean residual urine 156 ml. All patients underwent uneventful buccal mucosal graft dorsal on lay technique. At 3 months follow up, the mean Qmax was 23.2 ml/second with mean residual urine of 14 ml. A Self-reporting satisfaction scores using the Patient Global Impression of Improvement showed that seven patients scored 1 (very much better), four scored 2 (much better), two patients scored 3 (a little better), one patient scored 4 (no change) and none scored 5 (worse). No recurrence was noted.[53]

Venn et al compared outcome of patch vs tube graft in her study conducted on 39 patients who underwent a one-stage urethroplasty using buccal mucosa, 28 as a patch and 11 as tube grafts. Early results for patch urethroplasty were found encouraging with one recurrent stricture (3%) in the group with a patch urethroplasty vs recurrent stricture in five (45.5%) of the 11 patients with tube graft.[54]

In a similar study conducted by Andrich re-stricture rate was 11% for patch grafts and 45% for tube grafts.[55]

In a study conducted by Manjunath et al it was seen that for long segment anterior penile urethral strictures, unilateral mobilisation in BMG urethroplasty had shown success over both medium and long-term periods. A retrospective study was conducted in Kasturba Hospital, Manipal, Karnataka, India, from January 2008-December 2018. A total of 56 patients with long anterior segment penile urethral strictures underwent BMG substitution for urethroplasty, with a follow-up period ranging from

1.2-10 years. The mean age of 56 patients was 51.8±9.9 years, with a mean±Standard Deviation (SD) Maximum Flow Rate (MFR) of 20.1±5.3 mL at one month and 18.1±4.3 mL at three and 18.7±3.7 mL six months, 17.3±5.1 mL, 19.3±4.3 mL and 18.6±3.7 mL at one year, 2-5 years and 10 years postoperative respectively. Postvoid Residual urine (PVR) volume was higher till one year follow-up (i.e., first month it was 38.6±23.6 mL in 47 patients, third month it was 45.8±22.4 mL in 12 patients, sixth month it was 49.0±28.8 mL in 14 patients and one year follow-up it was 43.9±30.8 mL in 24 patients). Minimal complications were noted over 5-10 years follow-up.[56]

Soave et al conducted study to assess outcome of buccal mucosa graft urethroplasty (BMGU) for the treatment of urethral stricture disease. Median scores for ICIQ-MLUTS, IIEF-EF and EQ-5D visual analogue scale were 6, 22 and 80, respectively. Based on USS PROM, postoperative improvement of quality of life and satisfaction with BMGU was found in 67 patients (80.7%) and 68 patients (81.9%), respectively and was concluded that BMGU offers excellent success, morbidity and QoL.[57]

Similarly, D'Hulst et al evalualted success rate of BMGU through patient-reported outcome measures (PROMs) using five questionnaires: the International Prostate Symptom Score (IPSS); the IPSS Quality of Life questionnaire; the Urogenital Distress Inventory Short-Form questionnaire (UDI-6); the International Index of Erectile Function (IIEF)-5 questionnaire, combined with IIEF-Q9 and IIEF-Q10 for assessing ejaculatory and orgasmic functions; and the International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTS-QOL) questionnaire. Post operative follow up was done in three phases (median 2.1, 7.8 and 17.0 mths) and significant improvement was observed compared to baseline in IPSS, and IPSS-QOL, UDI-6 and ICIQ-LUTS-QOL scores at the first follow-up and remained improved during the

follow-up period (P ≤ 0.001). Patients with good baseline erections recovered erectile function during follow-up, although a significant decrease in erectile function was observed at the first follow-up.[58]

Ratnakar et al conducted a study on 43 patients with urethral strictures. He repaired the stricture with BMG urethroplasty and demonstrated that post-operative complications can occur in two areas: the site of harvest and the site of urethral stricture repair. Buccal mucosal harvest site complications included haemorrhage, pain, facial swelling, damage to Stensen's duct, lip paresthesia, numbness and restriction in mouth opening. Complications related to repair site included restricture , wound infection, urethrocutaneous fistula and meatal prolapse.[2]

In his study Jhunjhunwala et al concluded complications following reconstructive surgery for urethral stricture were mostly related to stricture recurrence (17.5%) or wound infection (15%) followed by permanent erectile dysfunction and anastomotic leak (5% each).[59]

Al Qudah et al conducted a study to extensively evaluate all early and late complications following urethroplasty. He studied 60 patients with mean follow up of 29mths and found early complications (in 40%) includedscrotal swelling, scrotal ecchymosis, urinary urgency and 3% were major (rectal injury and urosepsis). Late complications occurred in 48% which included a feeling of wound tightness, scrotal numbness , urine spraying and only 18% were significant (erectile dysfunction, chordee and fistula).[60]

In a study conducted on 128 patients by Spilotros et al most frequent complications recorded were urinary fistula (n=4; 3.1%), graft contracture (n=4; 3.1%) and graft failure (n=4; 3.1%). Complications were found to occur more commonly in complex stricture of the penile urethra.[61]

MATERIALS AND METHODS

It was a prospective study from December 2020 to March 2023. A total of 34 patients were enrolled in the study.

Inclusion Criteria

1. Strictures > 2.5cm in length
2. Patients requiring repeated internal urethrotomy or dilatations.

Exclusion Criteria

1. Periurethralphlegmon,
2. Multiple urethrocutaneous fistula,
3. Associated with chronic renal failure,
4. Scarred perineum.

The preoperative workup included careful general physical examination, palpation of the anterior urethra for any mass; glans penisinspected for signs of urethral meatal stenosis or balanitis xerotica obliterans. The perineum was inspected and examined for the presence of fistulas or periurethral inflammation. Dental surgeon's opinion was obtained regarding the hygiene of the oral cavity and to rule out any buccal mucosal pathology. The preoperative variables included in our study are age of the patients, duration and etiology of the stricture disease, preoperative uroflowmetry, history of previous urological intervention, stricture length as per preoperative retrograde urethrogram and intraoperative assessment. Undernasotracheal intubation, two teams were operating simultaneously in the oral cavity and the perineum. Perineum was explored with midline perineal incision. Bulbar urethra was circumferentially mobilized after separating the bulbospongiosus muscle. Strictured urethra and approximately 1.5 cm of normal urethra was mobilized proximally and distally. In case of pan urethral stricture penis was invaginated and the

urethra was separated from the corpus cavernosum up to the meatus. The urethra rotated and stricture was incised in the 12'0 clock position commencing at the distal end of the stricture and proceeding proximately till you get a healthy urethra admitting 22-26 Fr. bougies without difficulty. At this point length of stricture and surrounding spengiofibrosis assessed. If the dense stricture portion is 1.5-2 cm with extensive spongiofibrosis proximally or distally, that portion is excised. The urethral ends were spatulated dorsally and the ventral ends were-anastamosed with 4-0 vicryl, forming the floor strip, leaving a diamond shaped defect dorsally. The length of the stricture was measured. In the same time the oral surgical team harvests the buccal mucosal graft. The parotid duct was identified and desired buccal mucosal graft was outlined and margins infiltrated with sub mucosal injection of 1: 100,000 lignocaine in adrenaline. The graft was harvested minimizing fat in the undersurface while avoiding dissection into the muscle and going close to the gums. Donor site was left open. Depending on the length of stricture, buccal mucosal graft was harvested from one or both checks. The graft was defatted and fenestrated. The graft was secured to the cavemosa by interrupted vicryl sutures. Quilting sutures were placed through the graft into the underlying corporal surface along the length of the graft until the entire graft was secured. The right mucosal margin of the opened urethra is sutured to the right side of the patch graft, splaying open the strictured tract to new roof, which is the spread & fixed the graft. The urethra is rotated back to its original position. The left side of the urethra is sutured to the left side of the patch graft and to the corporal bodies. Bulbospongiosus muscle is reapproximated. Corrugated drain kept. An indwelling 16 Fr. Foley catheter is left in place. In cases with associated meatal stenosis it was addressed by dorsal on lay buccal mucosal graft with Blandy's type meatoplasty or ventral meatotomy. The decision of which procedure to perform and length of the buccal mucosal graft needed was partially based on the length and appearance of the stricture on

preoperative retrograde urethrography but predominantly on the intraoperative findings of stricture length as well as the appearance of the mucosa and spongy tissue.

Patient was started on oral fluid on 1st postoperative day and semisolid diet on day 2 and normal diet from day 3. The patient underwent pericatheter study on 21st post operative day and catheter was kept for one more week if it demonstrated leak. Patients asked to have a follow up visit at 1,3,6 months and yearly thereafter. They were evaluated with uroflowmetry and AUG. Success was defined as patient not needing any form of urethral instrumentation. Satisfactory result was defined as patient who needed urethral manipulation once. Failure was defined as patient who needs regular urethral dilatation by urologist or revision of urethroplasty or self urethral dilatation.

STATISTICAL ANALYSIS

The data so obtained was entered in Microsoft Excel and analyzed using descriptive statistics. It is described in terms of range; mean ± standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate.

All statistical calculations was done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

OBSERVATIONS AND RESULTS

AGE DISTRIBUTION

The majority of the patients were in the age group of 61 to 70 years constituting 26.5% of the total. The youngest patient was 20 years old and the oldest was 70 years. (Table1)

TABLE 1: DISTRIBUTION OF PATIENTS ACCORDING TO AGE GROUP

Age Group (years)	No. of Patients
20-30	8
31-40	7
41 – 50	4
51 – 60	6
61 – 70	9

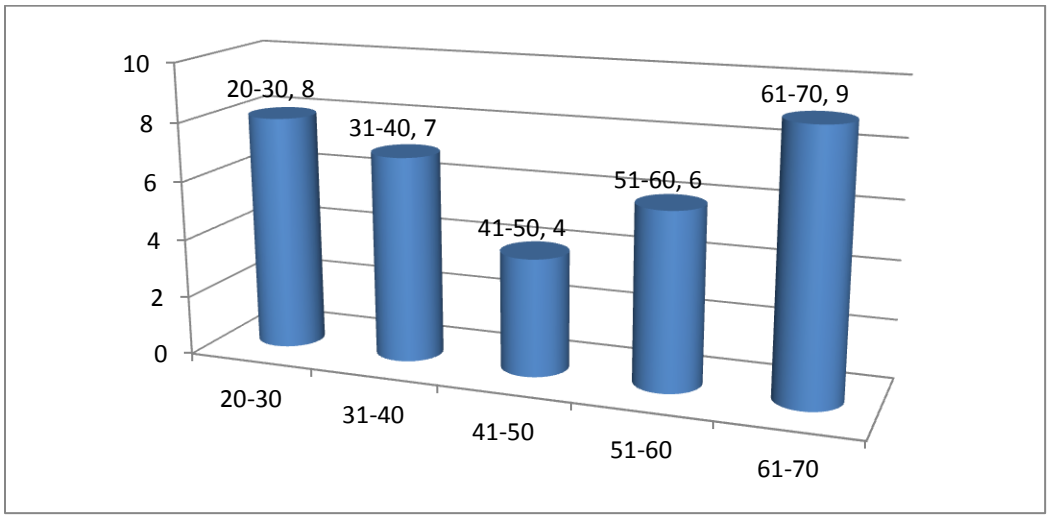

FIGURE 1: AGE DISTRIBUTION

STRICTURE ETIOLOGY

In majority of the patients, the stricture was caused due to BXO (64.7% of the total) followed by idiopathic (29.4%). One patient had post inflammatory stricture and one had post infection stricture.

TABLE 2: ETIOLOGY OF STRICTURE

Etiology of Stricture	No. of Cases
Balanitis xerotica obliterans	22
Idiopathic	10
Post inflammatory	1
Post instrumentation	1

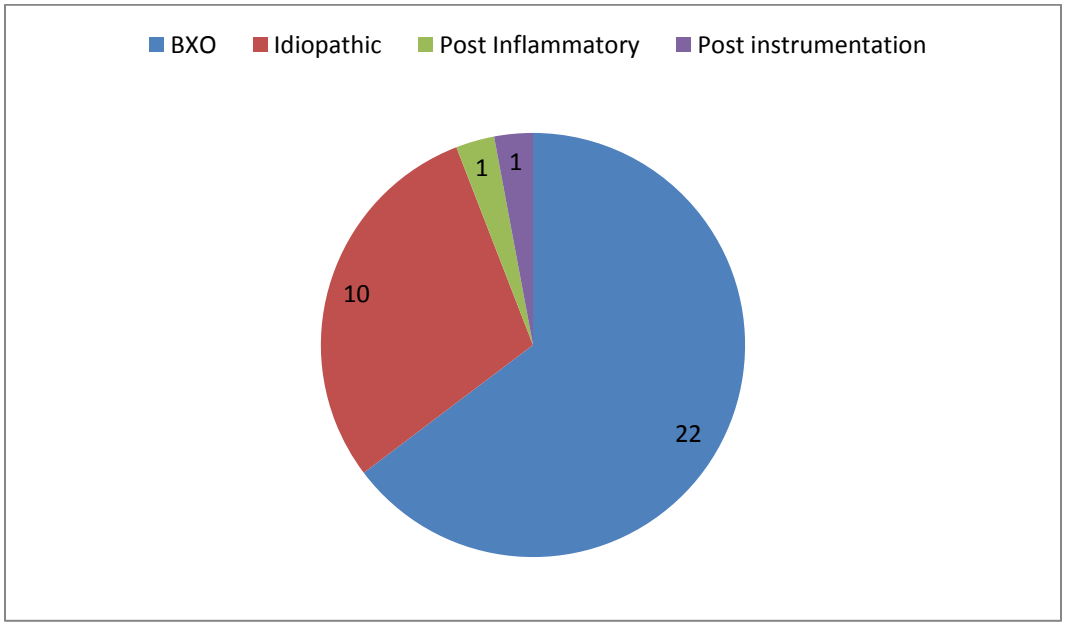

FIGURE 2: ETIOLOGY OF STRICTURE

STRICTURE LENGTH AND MEATAL STATUS

Maximum stricture length encountered was 12 cm and minimum was 3.5cm. Seven patients due to balanitis xerotica obliterans were associated with meatal stenosis.

TABLE 3: LENGTH OF THE STRICTURE AND METAL STATUS

Length of Stricture	No. of Patients	External urethral meatus
2 – 6 cms	12	Normal
6.5 – 10 cms	21	6 meatal stenosis
> 10 cms	1	1 meatal stenosis

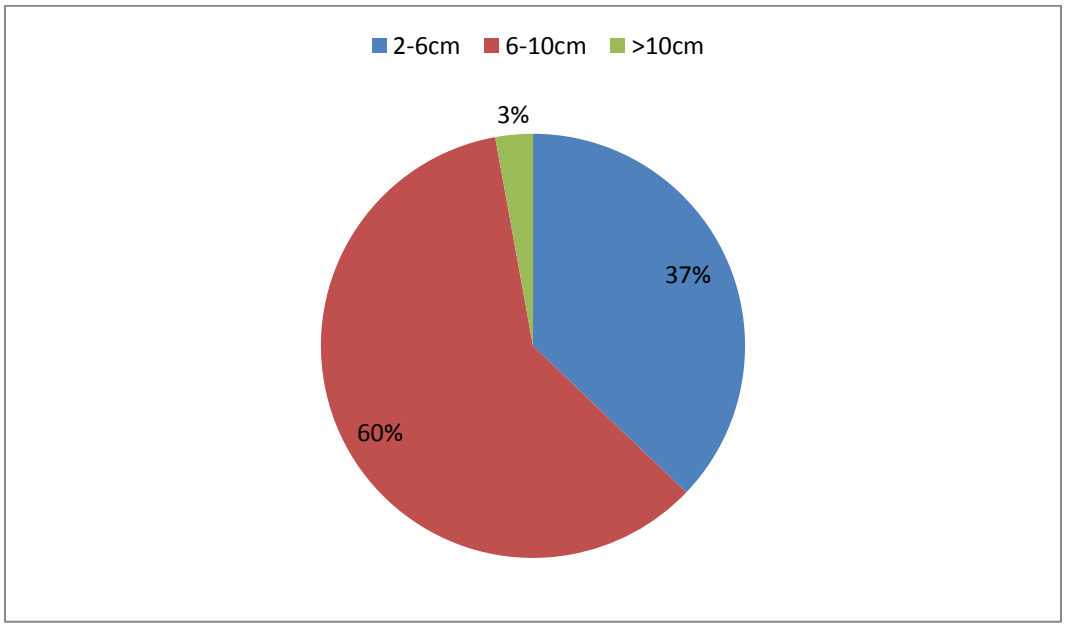

FIGURE 3: LENGTH OF THE STRICTURE AND METAL STATUS

OPERATIVE PROCEDURE

All the patients with medium length stricture (2-6cm) underwent dorsal onlay urethroplasty (12). Of the long strictures (>6cm), for most of the patients dorsal onlay urethroplasty was done (14) followed by Blandys meatoplasty with dorsal onlay graft urethroplasty (6) followed by ventral meatotomy and dorsal onlay graft urethroplasty (3).

TABLE 4: OPERATIVE PROCEDURE

Classification	Procedure	No. of grafts used	No. of patients
Medium length Stricture	Dorsal on lay graft Urethroplasty.	12	12
Long Stricture	Ventral meatotomy& Dorsal on lay graft Urethroplasty	3	2
	Blandy'smeatoplasty& Dorsal on lay graft Urethroplasty	6	6
	Dorsal on lay graft Urethroplasty	14	14

UROFLOWMETRY RESULTS

Uroflowmetry was done in petients PRE operatively and post operatively after catheter removal. In all the cases increase in post operative values as compared to PRE operative values was seen.

TABLE 5: PREOPERATIVE UROFLOWMETRY

Classification	**Peak flow rate**	**Average flow rate**	**Voided volume**	**Not able to void on SPC**
Medium length stricture	**PRE** 7.8 to 11.4 ml/sec	3.4 to 6.5 ml/sec	150 to 350 ml	Nil
	POST 22 to 40 ml/sec	16 to 28 ml/sec	300 to 400 ml	
Long Stricture	**PRE** 5.4ml to 6 ml/sec	2.6 to 3.4 ml/sec	120 to 180 ml	8 Patients
	POST 20 to 37 ml/sec	14 to 26 ml/sec	300 to 400ml	

PERICATHETER STUDY

In the group of patients with long strictures 82%of them had no leak and had their catheter removed on 21st postoperative day, 18% of patients had no leak and had their catheter removed on 28thpost operative day.

TABLE 6: PERICATHETER STUDY

Classification	No. of Pericatheter studies	No. of no leaks & Catheter removal on 21st POD	No. of no leaks & catheter removal on 28th POD
Medium length strictures	12	11	1
Long strictures	22	18	4

OUTCOME

Medium length stricture showed 100% success rate. Long urethral stricture had a successful treatment in 15/22 patients (68%) satisfactory result in 4/22 patients (18%) and failure in 3 patients who needed self urethral dilatation & perineal urethrostomy (13.6%).

TABLE 7. OUTCOME IN LONG STRICTURE

SUCCESSFUL	**15**
SATISFACTORY	**4**
FAILURE	**3**

DISCUSSION

In patients whose age was more than 60 years, were thoroughly evaluated for systemic diseases like diabetes mellitus, hypertension, cardiac or renal failure, intercurrent illness and benign prostatic hyperplasia.

Majority of the patients, the stricture was caused due to BXO. In 10 patients cause was not known. One patient had post inflammatory stricture.

Fourteen patients already underwent visual internal urethrotomy 1-5 times each. Four patients were not able to cope up with self-urethral dilatation program. Two patients underwent urethral dilatation by the urologist. Twenty patients were circumcised. Initially in our study buccal mucosal graft urethroplasty was offered to patients who had failed in traditional from of urethral stricture management like internal urethrotomy and urethral dilatation. As our experience accumulated, it was offered to long urethral stricture disease patients in the first instance. Six patients were on urinary diversion for a period of 3 months to 1years. The patients were suffering from stricture disease for a period of 1 month to 12 years.

Stricture was assessed radiologically with retrograde urethrogram. They were classified into medium length strictures (2-6 cm) and long segment strictures (>6 cms).

Since most of the stricture disease was due to balanitis xerotica obliterans the number of longer strictures were in high proportion. Preoperative stricture length was increased at least by 2 cm from the radiological length assessed by retrograde urethrogram. Seven patients due to balanitis xerotica obliterans were associated with meatal stenosis. The maximum length of stricture encountered was12cms.

The preoperative uroflowmetry was performed in patients who were able to void and not on suprapubiccystostomy. Postoperative uroflowmetry was

done after catheter removal and values were compared. For all cases both medium and long strictures, all values were found to improve.

Christopher J Kane et al did retrospective analysis on 53 patients who underwent buccal onlay urethroplasty. Post operative uroflowmetry values seemed to improved when compared to PRE operative values. Average peak flow rates increased from 7.9 ml/sec to 30.1 ml/sec.[44]

The oral swelling and pain subsided on 4th postoperative day so as to allow normal diet in patients. In five patients the swelling took six days to subside. None of them had parotid duct obstruction.

The pericatheter study was performed in all patients. In two patients with medium length bulbar urethral stricture who had 16Fr. Silicon Foley, Foley got extruded due to balloon failure.

In the group of patients with long strictures 82%of them had no leak and had their catheter removed on 21st postoperative day, 18% of patients had no leak and had their catheter removed on 28th post operative day. Thehighincidenceofleakinpericatheterstudyinpatientswithlongstrictures may be due to the extensive dissection or poor vascularity associated with pan urethral strictures.

One patient developed urethrocutaneous fistula that healed with prolonged catheter drainage. Three patients developed epididymoorchitis which was managed with good urethral nursing and antibiotics. Two patients had transient terminal haematuria which settled with conservative line of treatment. One patient had mild restriction in opening the mouth. Three patients had donor site numbness which settled on follow up.

One bulbar urethral narrowing patient underwent two time visual internal urethrotomy and he is on regular dilatation. One patient had leak in the pericatheter study. The follow up urethrogram of the patient showed evidence of graft loss. The patient underwent visual dilatation of the

strictured segment and advised periodic urethral dilatation (once in a month). Patient reviewed after 2 months. He had recurrent stricture and perineal urethrostomy was done.

Medium length stricture showed 100% success rate. Long urethral stricture had a successful treatment in 15/22 patients (68%) satisfactory result in 4/22 patients (18%) and failure in 3 patients who needed self urethral dilatation & perineal urethrostomy (13.6%).

Morey and Mac Aninch reported 100% success rate in 13 patients who underwent ventral onlay BMG urethroplasty for anterior urethral stricture.[62]

Barbagli et al conducted a study in 45 patients in which penile skin was used as a graft. 27% of the cases were labelled as failure. They concluded that penile skin grafts used in dorsal onlay urethroplasty showed tendency to deteriorate with time.[43]

SUMMARY AND CONCLUSION

SUMMARY

1. Balanitis xerotica obliterans was the commonest cause of stricture we had encountered.
2. Meatal stenosis was present in 36% of the long anterior urethral stricture group.
3. Buccal mucosal donor site healed with minimum complications.
4. Leak in pericatheter study and age did not adversely affect the end result.
5. Restricture occurred in the sub meatal and proximal anastamotic site with the intervening graft healthy.
6. Of the 34 graft used one graft loss has occurred.
7. Medium length bulbar urethral strictures had 100% result at the end of follow up
8. Urethrocutaneous fistulas requiring surgical correction did not occur in our series even in pan urethral strictures.
9. Long urethral stricture had a successful treatment in 15/22 patients (68%) satisfactory result in 4/22 patients (18%) and failure in patient who needed self urethral dilatation & perineal urethrostomy(13.6%)

CONCLUSION

1. Buccal mucosal graft has good graft properties for graft survival with minimal donor site morbidity.
2. Dorsal onlay graft is the preferred form of graft placement.
3. Buccal mucosal graft is an ideal substitute for urethra in treating medium length bulbar urethral stricture.
4. Because of less failure rate it can be offered as an alternative to staged urethroplasty in case of long urethral stricture.

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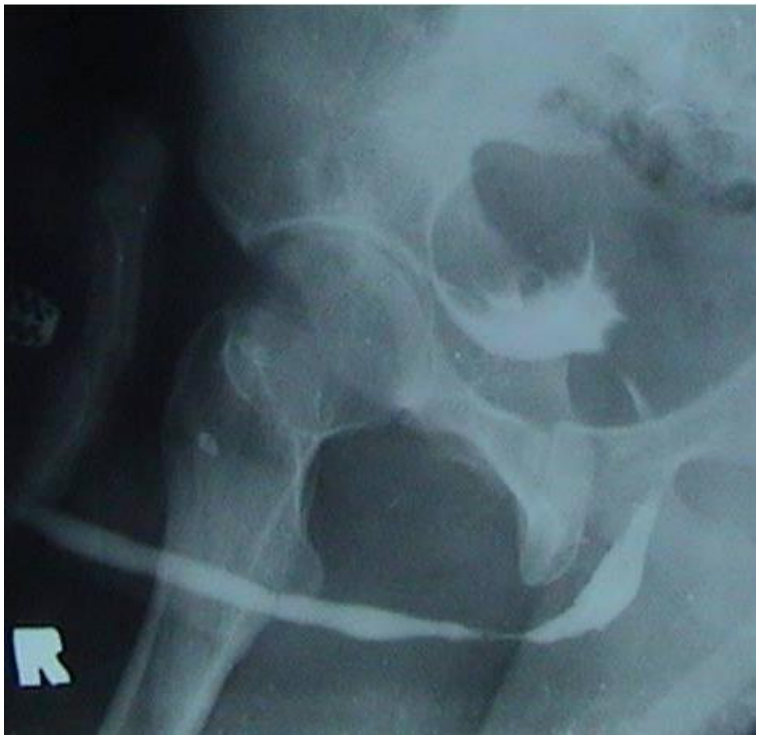
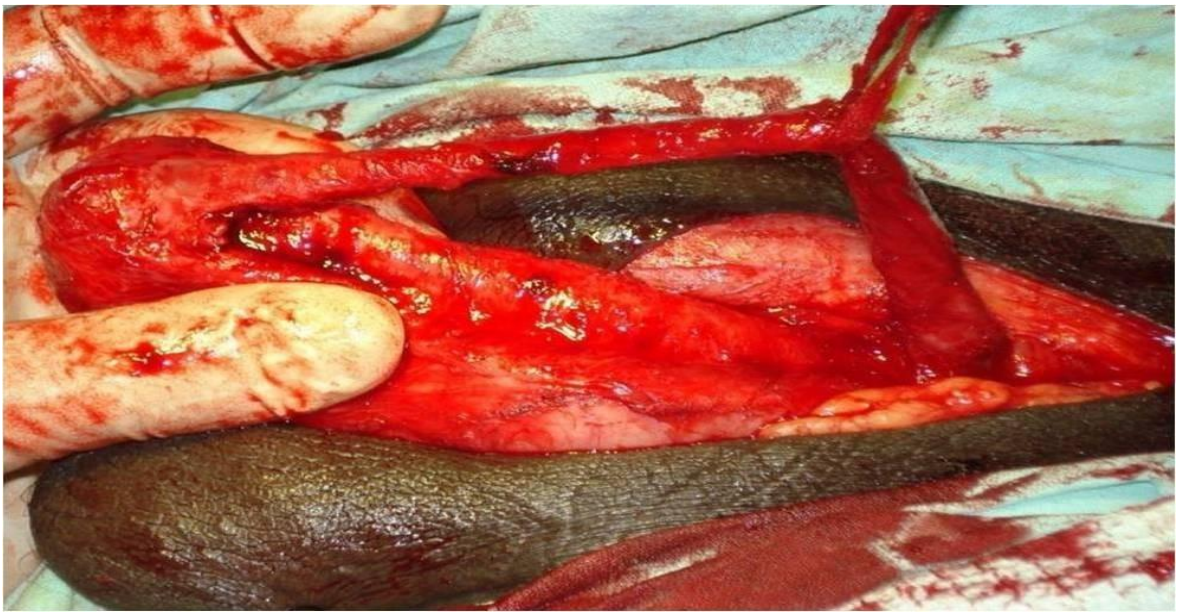
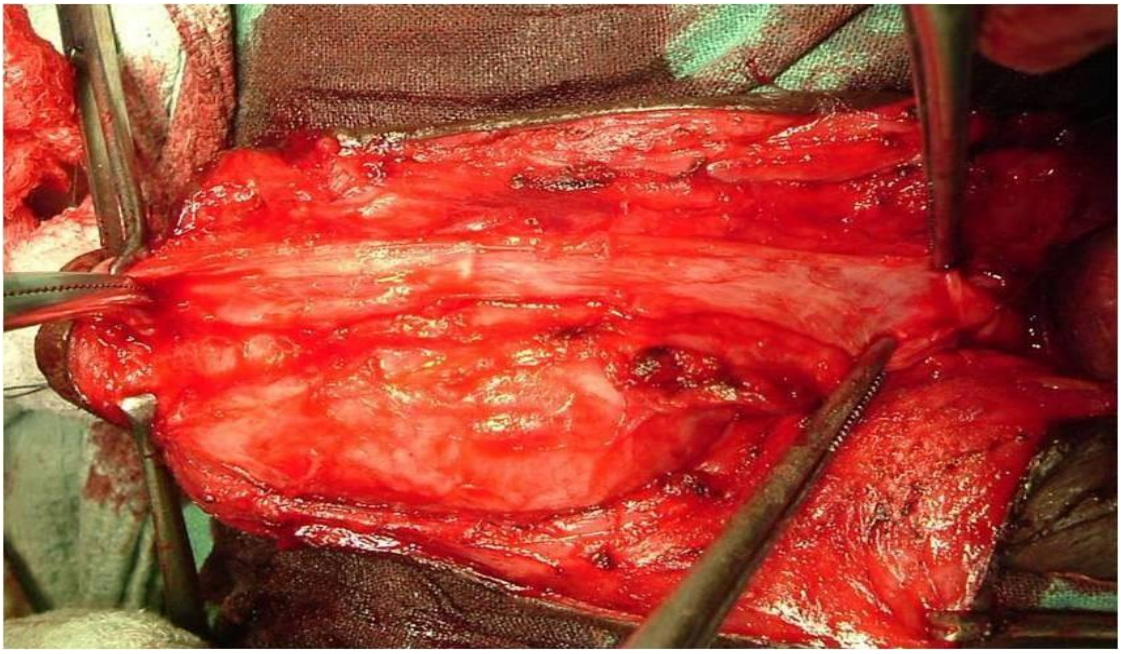
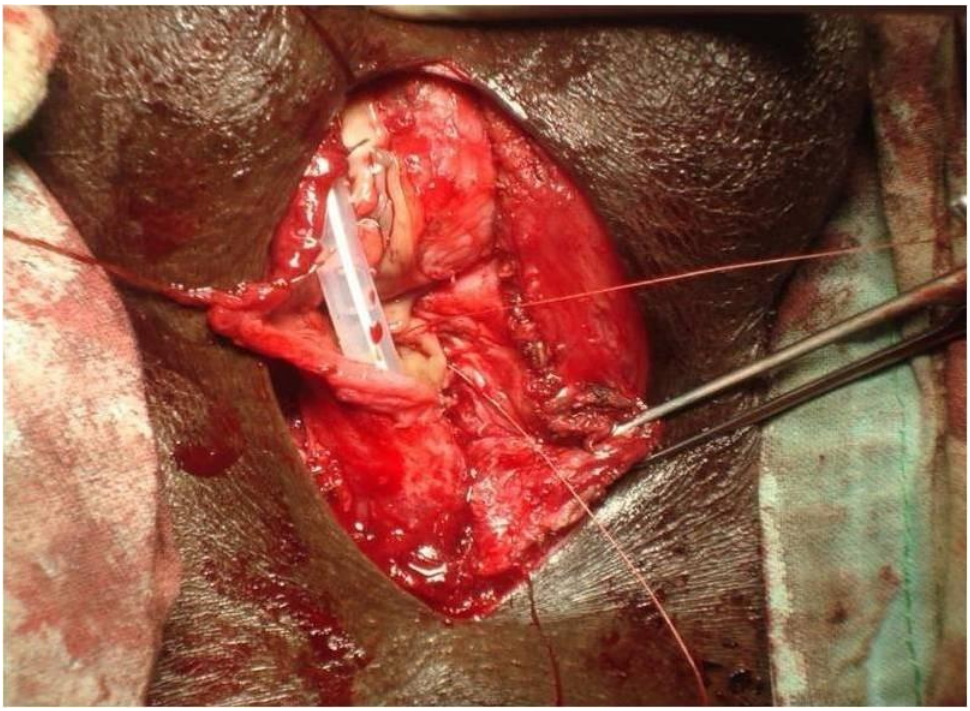
PICTURE 1: PRE-OPERATIVE AUG



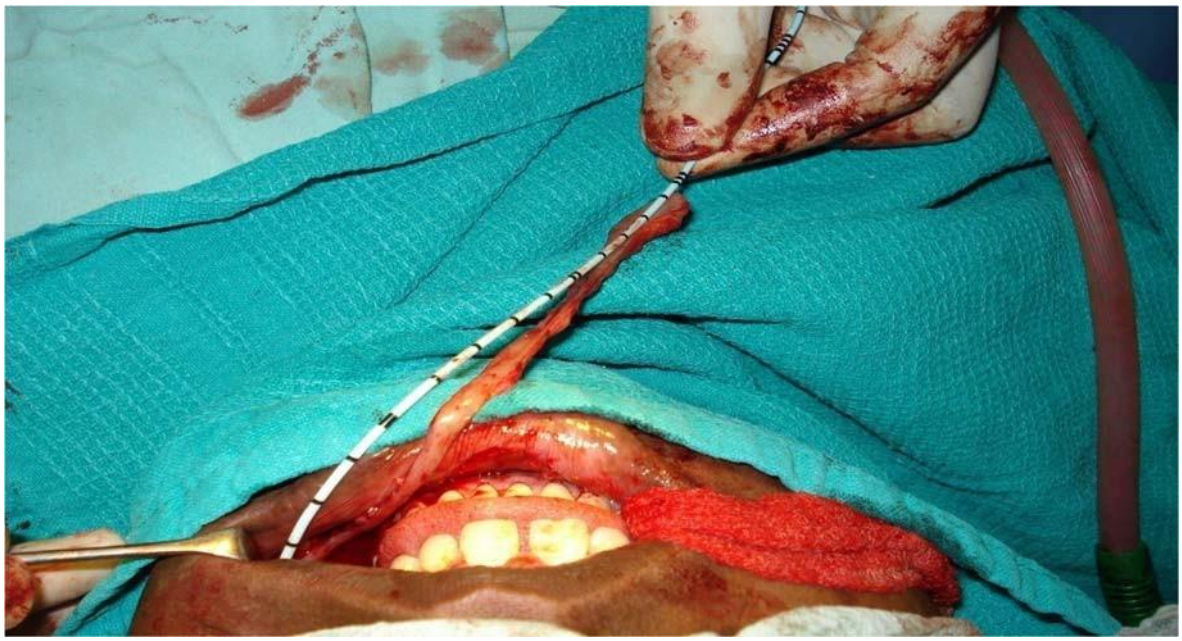
PICTURE 2: OPERATIVE PICTURES

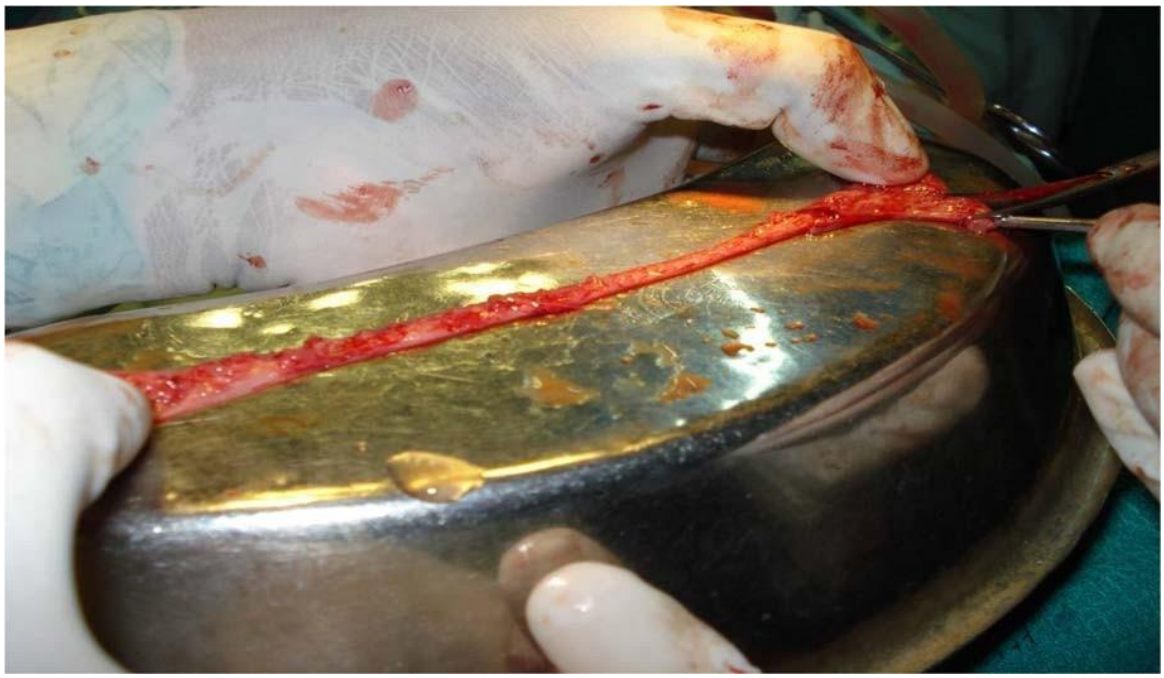






PICTURE 3: BUCCAL MUCOSAL GRAFT

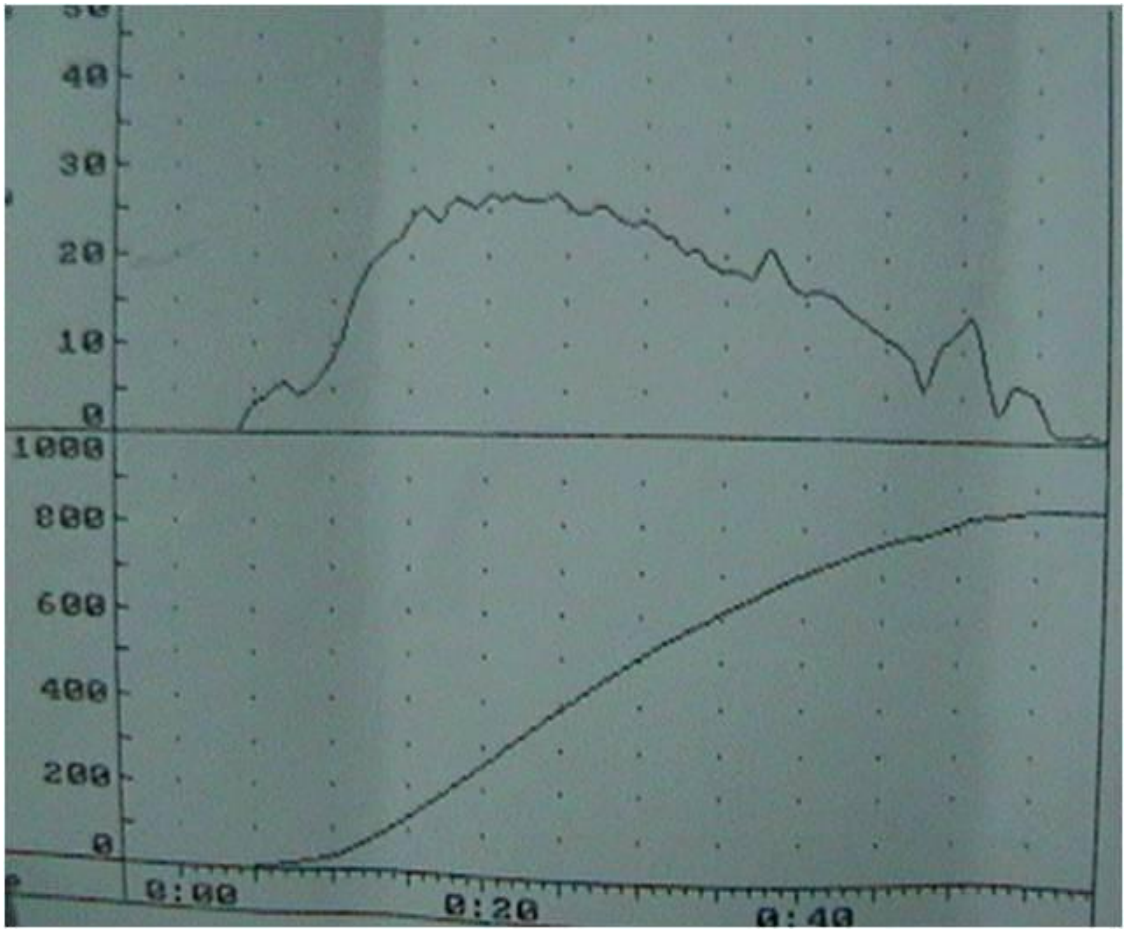




PICTURE 4: WOUND CLOSURE

PICTURE 5: POST OP AUG

PICTURE 6: POST OP UROFLOW



MASTER CHART

Sl. No.	Name	Age	Length Cms	Cause	Pre-operative			Post-operative		
					Peak Flow ml/sec	Mean flow ml/sec	Voided volume ml	Peak Flow ml/sec	Mean flow ml/sec	Voided volume ml
1.	AP	57	3.5	BXO	7.8	6	260	22	18	350
2.	MS	55	7	Idiopathic	5	3	150	28	21	400
3.	JS	50	12	BXO with Meatal Stenosis	SPC			22	18	350
4.	GG	38	8	BXO	5.5	2	160	26	20	350
5.	RS	53	5	Idiopathi	10	6	300	32	19	400
6.	DS	33	8	BXO with Meatal Stenosis	6	3	200	30	20	350
7.	PS	62	6.5	BXO	SPC			37	19	300
8.	R	25	4.5	BXO	8	4	270	28	18	400
9.	AS	30	9.4	BXO	4	3	130	24	18	350
10.	KS	21	9	BXO with Meatal Stenosis	SPC			26	17	300
11.	BS	53	8.8	BXO	9	6	350	28	19	350

12.	S	64	4	Idiopathic	8	6	400	32	22	400
13.	DS	44	9	BXO	4	3.2	160	34	18	400
14.	J S	28	5.6	Idiopathic	11	5	300	22	18	400
15.	KS	64	7	BXO	5	3	200	20	16	350
16.	SR	63	6.5	BXO with Meatal Stenosis	SPC			22	16	300
17.	SS	70	7	BXO	4	3	150	32	22	400
18.	SM	62	6	Idiopathic	6	3	200	28	20	300
19.	HR	34	9	BXO with Meatal Stenosis	SPC			29	23	300
20.	SS	70	8	Post inflammatory	4	2	170	28	20	400
21.	JS	32	5	BXO	8	6	270	40	24	350
22	BS	36	9	Idiopathic	5	3	180	26	20	300
23.	G S	27	4	Post Instrumentation	9	4	300	24	18	350
24.	KS	25	4.5	Idiopathic	8	5	300	20	16	350
25.	VS	42	8	BXO with Meatal Stenosis	5	2	150	18	14	300
26.	SS	29	9	Idiopahic	6	3	180	28	20	400

27.	S .S	42	4	Idiopathic	SPC			26	19	400
28.	A .k	37	8.4	BXO	5	3	190	20	18	400
29.	J .P	38	5	BXO	6	4	270	24	20	400
30.	D .S	56	9.2	BXO	4	2	180	26	24	350
31.	G.S	62	4.8	Idiopathic	7	4	300	24	28	400
32.	S.S	60	9	BXO	5	3	150	32	26	350
33.	S.K	20	9	BXO with Meatal Stenosis	SPC			20	16	300
34.	R.S	53	7	BXO	4	2	220	20	14	350

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No. BFUHS/2K21p-TH/ 71

Date 25/10/21

The Principal,
DMC, Ludhiana.

Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Sunit Tandon**, a student of your college for **MCh Urology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Study to evaluate the outcome of buccal mucosal graft urethroplasty in anterior urethral stricture.

Supervisor
Dr. Harmandeep Singh Chahal
Assoc. Prof.,
Dept. of Urology,
DMCH, Ludhiana.

Co-Supervisor

Dr. Sandeep Sharma
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Dr. Rajinder Mittal
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Dept. of Plastic Surgery,
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The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

185. If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.

186. The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.

A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN PATIENTS WITH ANTERIOR URETHRAL

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MCh

IN

UROLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES
FARIDKOT

AUGUST, 2021

DR. SUNIT TANDON

DEPARTMENT OF UROLOGY
DAYANAND MEDICAL COLLEGE & HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE
For the degree of	MCh Urology
Name of the candidate	Dr.SUNIT TANDON
Supervisor	Dr. Harmandeep Singh Chahal, Associate Professor, Department of Urology, DMCH
Co-supervisor	Dr. Sandeep Sharma, Professor & Head, Department of Urology, DMCH Dr. Rajinder Mittal, Professor & Head, Department of Plastic Surgery, DMCH
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Urethral stricture is the common cause of morbidity in men. These are narrowing of the urethral lumen because of ischaemia of corpus spongiosum. The narrowing causes obstructive voiding dysfunction and irritative urinary symptoms which can lead to impaired renal function. Numerous surgical techniques have been described over the years and gradually refined. The exact choice of technique depends on numerous factors like: previous surgery, number of strictures, length of stricture, stricture location, stricture etiology, comorbidities, the quality of the corpus spongiosum, surrounding tissues and potential graft sites. Urethroplasty is considered to be the gold standard for management of urethral stricture. Of the various types of urethroplasty, buccal mucosal graft has most favourable outcome.

Aim of Study: To evaluate the outcome of buccal mucosal graft urethroplasty in anterior urethral stricture

Materials & methods: The study will be conducted among the patients admitted to Department of Urology, Dayanand Medical College and Hospital, Ludhiana. The data for the study subject will be retrospectively and prospectively from 1st August 2021 to 1st January 2023. Data shall be collected through a pre- designed performa for each patient with detailed history, clinical examination and complete investigational workup. A pre-informed consent from each patient shall be taken. Details of the study will be explained to each patient. Analysis will be done with the collected data.

Keywords: urethral stricture, urethroplasty, buccal mucosal graft.

(Signature)	(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-supervisor	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE"** exist in the Department of Urology, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate himself/herself under our supervision and guidance.

Supervisor

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APPROVAL PROFORMA
BYRESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr.SunitTandon
Department	MCh Urology
Topic of Thesis	STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE
Likely date of appearing in PG examination	MAY/JUNE, 2023
Date of enrollment	31.12.2020
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1) Supervisor **2) Co-Supervisor** **Co-Supervisor**	Dr. Harmandeep Singh Chahal Dr. Sandeep Sharma Dr. Rajinder Mittal
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
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	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / No

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Approved: Yes / ~~No~~

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BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	DR. SUNIT TANDON
2	NAME OF THE INSTITUTE	DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA
3	COURSE OF STUDY AND SUBJECT	M.Ch UROLOGY
4	DATE OF ADMISSION OF COURSE	31st December 2020.
5	TITLE OF THE TOPIC	STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

The male urethra is divided into anterior urethra and posterior urethra. The posterior urethra includes prostatic urethra and membranous urethra. The anterior urethra includes penile urethra and bulbar urethra. [1]

The penile urethra is surrounded by corpus spongiosum which lies in the ventral groove between the two corpora cavernosa. The tunica albuginea of the corpus spongiosum is thinner than that of corpora cavernosa. The urethra traverses the length of the penis within the corpora spongiosum. At its distal end the corpus spongiosum expands to form the glans penis, a broad cap of erectile tissue covering the tips of corpora cavernosa. [1]

Bucks fascia is the tough, elastic layer immediately adjacent to the tunica albuginea. On the superior aspect of the corpora cavernosa, deep dorsal vein, paired dorsal arteries & multiple branches of dorsal nerves are contained within the envelope of Buck's fascia. In the midline groove, on the undersurface of corpora cavernosa, Buck's fascia splits to surround the corpora spongiosum. Consolidations of the fascia, lateral to the corpora spongiosum, attach it to the lateral surface of corpora cavernosa. Attached distally to the undersurface of the glans penis at the corona, Buck's fascia extend into the perineum, enclosing each crus of the corpora cavernosa and bulb of the corpus spongiosum. It firmly fixes these structures to the pubis, ischium and inferior fascia of perineal membrane (urogenital diaphragm).[1]

Anterior urethra extends from the inferior fascia of the urogenital diaphragm to the external meatus of the penis. For better understanding of discussion about reconstruction of urethra it is subdivided into three regions. [1]

Fossa navicularis is contained within the spongy erectile tissue of glans penis & it terminates at the junction of urethral epithelium with the skin of glans. This portion of urethra is lined with stratified squamous epithelium.[1]

The penile or pendular urethra lies distal to the investment of ischiocavernous musculature but it is invested by the corpus spongiosum. The penile urethra is lined with simple squamous epithelium. [1]

The bulbous urethra is covered by the midline fusion of the ischiocavernous musculature and is invested by the bulbospongiosus & corpus spongiosum. It becomes larger & lies close to the dorsal aspect of corpus spongiosum, exiting at its dorsal aspect, before the posterior attachment of the bulbospongiosus to the perineal body. The bulbous urethra is lined with squamous epithelium which changes to transitional epithelium at the level of membranous urethra.[1]

Urethral stricture is the common disease, which has affected mankind since the beginning.[2] Urethral strictures are narrowing of the urethral lumen because of ischaemic spongiofibrosis.[3] The narrowing causes obstructive voiding dysfunction and irritative urinary symptoms which can ultimately impair renal function.[4] Worldwide prevalence of urethral strictures is estimated to be 229-627/100,000.[5]

The etiology of urethral strictures is divided into four major groups: idiopathic, iatrogenic, inflammatory, and traumatic. Most common being idiopathic and iatrogenic (33% each) followed by traumatic causes comprising 19% and finally inflammatory, causing 15% of them. [5]

Iatrogenic causes include transurethral resection (TUR- 41%), prolonged catheterization (36%), cystoscopy (12.7%), hypospadias repair (6.3%) and prostatectomy (3.2%).[5]

Among inflammatory are post infectious (most commonly from recurrent gonococcal urethritis), recurrent urinary tract infections (UTIs) (with the most isolated microorganism being Escherichia coli). Lichen sclerosis (LS) is another cause. Inflammatory strictures only affect the anterior part and do not extend to cause posterior urethral strictures.[5]

Trauma related urethral strictures are frequently due to straddle injuries compressing the bulbar urethra against the symphysis pubis. This pattern of injury is rarely associated with a pelvic fracture. Traumatic strictures tend to be short, with most of them less than four cm in length. [5]

Table showing age wise distribution of stricture etiology in India: [6]

Cause		Age : 40yrs or less	Age : 40yrs or greater	Value
Idiopathic		63	49	<0.05
Iatrogenic	Urethral Catheterization	19	39	not significant
	TUR	5	58	<0.05
	Cystoscopy	0	10	not significant
	Prostatectomy	0	7	<0.05
	Brachytherapy	0	7	<0.05
	Hypospadias Repair	22	2	<0.05
Inflammatory	Urethritis	20	21	not significant
Lichen Sclerosis		12	27	not significant
Traumatic	Perineal Trauma	4	5	not significant
	Pelvic Fracture	26	9	<0.05
	Penile Fracture	3	1	not significant
Total (404)		171	233	

These patients present with weak stream, straining to urinate, incomplete emptying, post-void dribbling, urinary retention and recurrent urinary tract infections. On examination, associated spongiofibrosis may be palpated periurethrally.[7]

Patient may even present with hematuria or pollakisuria which are likely to be the result of a stricture related complication such as urinary stones, urethritis or an infection of the prostate, epididymis or testicle.[8]

Combination of both RUG and VCUG provides a comprehensive image of the entire urethra and reveals valuable information about the number of strictures, stricture length, stricture location and the remaining caliber of the narrowed urethra.[8]

Ultrasonography is useful in the diagnostic work-up of urethral strictures as it measures stricture length more adequately and provides information about the surrounding spongiofibrosis.[8] Magnetic resonance imaging (MRI) is useful in diagnosis of tumor related urethral stricture disease. CT voiding urethrography provides important information in case of stricture related fistulas.[8] Uroflowmetry is useful in assessment of the urethral flow. A maximum flow (Qmax) of less than 15 mL per second raises the suspicion of lower urinary tract stricture. Urethral strictures typically produce a plateau at the level of Qmax.[5] Urethroscopy/cystoscopy is a relatively quick and easy investigation that helps to determine the location of the stricture.[5]

Various treatment modalities for urethral stricture include dilations, endoscopic treatment (Direct Vision Internal Urethrotomy (DVIU), Metallic Endoluminal Stents, Laser Evaporation of the Stricture and Open Reconstructive Treatment (Urethroplasty))[8]

Urethral strictures can lead to various complication like: recurrent UTI, acute urinary retention, bladder diverticulum, urethrocutaneous fistula, bilateral or unilateral vesicoureteric reflux.[5] Surgery related complications include: bleeding, infection, incontinence, impotence and stricture recurrence.

We will evaluate the outcome of buccal mucosal graft urethroplasty in patients with anterior urethral stricture in our institute.

6.2 REVIEW OF LITERATURE

URETHROPLASTY

Over time, numerous surgical techniques have been described and gradually refined. The exact choice of technique depends on numerous factors like: previous surgery, number of strictures, stricture length, stricture location, stricture etiology, comorbidities, the quality of the corpus spongiosum, surrounding tissues and potential graft sites.[7] Urethroplasty is considered to be the gold standard for management of urethral stricture by most of the urologists. Various studies conducted for both excisional urethroplasty and use of grafts show higher long-term success rates than any other form of management of urethral strictures.[9]

Wong et al conducted a study in which he compared the outcomes of urethrotomy and urethroplasty in 50 men with traumatic stricture of the posterior urethra following pelvic fracture injury. In the first six months, men were more likely to require further surgery in the urethrotomy group than in the primary urethroplasty group (RR 3.39, 95% CI 1.62 to 7.07). After two years, 16 of 25 (64%) men initially treated by urethrotomy required continued self-dilatation or further surgery for stricture recurrence compared to 6 of 25 (24%) men treated by primary urethroplasty.[10]

Anastomotic urethroplasty involves stricture resection and end-to-end anastomosis. It is mostly done when the stricture is short (<2 cm) and is in the bulbar urethra, which is usually the result of a traumatic straddle-type injury.[5]

In substitution urethroplasty or graft urethroplasty the urethra is mobilized in the area of stricture, dissected from the corpora cavernosa and opened along the urethra for the entire length of the stricture. This can be done through ventral, dorsal or lateral approach. Following this, a skin graft is sutured to the defect to create a wider urethra.[5]

Split and full thickness skin grafts can be taken from different sites like: scrotum, penis, extragenital sites (ureter, saphenous vein, appendix, colon, medial upper arm, neck, lateral chest, abdomen, bladder mucosa) and more recently oral mucosa has been used. Oral mucosa

grafts have various favorable properties as they are flexible, easy to harvest, trim and have an excellent microvasculature favorable for graft-taking. Due to its natural moist location oral mucosal graft adapts easily in the urethral passage thus giving good long-term results.[11]

Lumen et al reviewed 18 papers for analyzing the efficacy of penile skin graft (PSG) vs buccal mucosal graft (BMG). In total, 428 and 483 patients were respectively treated with PSG or BMG. Follow-up duration was 64.1 versus 42.1 months ($p < 0.0001$) and stricture length 6.2 versus 4.6 cm ($p < 0.0001$) for PSG and BMG, respectively. Success of urethroplasty with PSG was 81.8% versus 85.9% with BMG ($p = 0.01$).[12]

Buccal mucosal grafts are mainly used in two cases. Most commonly, for ventral-onlay buccal urethroplasty for bulbar stricture and less commonly to augment an inadequate urethral plate during first stage Johanson urethroplasty, usually for penile stricture. Buccal-augmented Johanson urethroplasty is found to be especially useful in patients with lichen sclerosis and strictures after childhood hypospadias repair.[13]

Pahwa et al conducted a study in which Asopa and Barbagli techniques of BMG urethroplasty were compared. Asopa technique was found to take lesser time to perform as compared to the Barbagli (142 versus 125 minutes). Cases where anterior urethra was found to be densely adhered to corpus cavernosum due to extensive spongiofibrosis, Asopa technique was found to be more suitable. The complication rate was found to be equal in both the approaches. In this series, 18 out of 20 patients were voiding satisfactorily at one-year follow-up in each group and postoperative imaging study in these patients showed a good lumen with no evidence of leak or extravasation. Hence no statistically significant difference was found in use of either of techniques.[14]

Study conducted by Barbagli et al showed that placement of buccal mucosa grafts into the ventral, dorsal or lateral surface of the bulbar urethra bear same success rates (83% to 85%) and the outcome was not affected by the surgical technique.[15]

Khwaja et al showed that for female urethral stricture reconstruction, dorsal buccal mucosal graft currently represents a prime choice. He performed dorsal buccal mucosal graft urethroplasty on 25 female patients aged 22 to 66 years and followed up them with lower urinary tract symptom, uroflowmetry and post-void residual urine assessments. Success rate was found to be >90% with mean pre- versus postoperative Qmax being 5 ml/s versus 23.3 ml/s and mean residual urine being 178 ml versus 18.5 ml. [16]

Outcome of patch vs tube graft was compared in the study conducted by Venn et al on 39 patients who underwent a one-stage urethroplasty using buccal mucosa, 28 as a patch and 11 as tube grafts. Early results for patch urethroplasty were found encouraging with one recurrent stricture (3%) in the group with a patch urethroplasty vs recurrent stricture in five (45.5%) of the 11 patients with tube graft. [17]

In a similar study conducted by Andrich, re-stricture rate was 11% for patch grafts and 45% for tube grafts. [18]

Study was conducted by Soave et al to assess outcome of buccal mucosa graft urethroplasty (BMGU) for the treatment of urethral stricture disease. Median scores for ICIQ-MLUTS, IIEF-EF and EQ-5D visual analogue scale were 6, 22 and 80, respectively. Based on USS PROM, postoperative improvement of quality of life and satisfaction with BMGU was found in 67 patients (80.7%) and 68 patients (81.9%), respectively and was concluded that BMGU offers excellent success, quality of life and less morbidity.[19]

Similarly, D'Hulst et al evaluated success rate of BMGU through patient-reported outcome measures (PROMs) using five questionnaires: the International Prostate Symptom Score (IPSS); the IPSS Quality of Life questionnaire; the Urogenital Distress Inventory Short-Form questionnaire (UDI-6); the International Index of Erectile Function (IIEF)-5 questionnaire, combined with IIEF-Q9 and IIEF-Q10 for assessing ejaculatory and orgasmic functions; and the International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTS-QOL) questionnaire. Post operative follow up was done in three phases (median 2.1, 7.8 and

17.0 months) and significant improvement was observed compared to baseline in IPSS, and IPSS-QOL, UDI-6 and ICIQ-LUTS-QOL scores at the first follow-up and remained improved during the follow-up period ($P \leq 0.001$). Patients with good baseline erections recovered erectile function during follow-up, although a significant decrease in erectile function was observed at the first follow-up.[20]

Ratnakar et al conducted a study on 43 patients with urethral strictures. He repaired the stricture with BMG urethroplasty and demonstrated that post-operative complications can occur in two areas: the site of harvest and the site of urethral stricture repair. Buccal mucosal harvest site complications included haemorrhage, pain, facial swelling, damage to Stensen's duct, lip paresthesia, numbness and restriction in mouth opening. Complications related to repair site included restricture, wound infection, urethrocutaneous fistula and meatal prolapse. [2]

In his study Jhunjhunwala et al concluded that complications following reconstructive surgery for urethral stricture were mostly related to stricture recurrence (17.5%) or wound infection (15%) followed by permanent erectile dysfunction and anastomotic leak (5% each).[20]

Al Qudah et al conducted a study to extensively evaluate all early and late complications following urethroplasty. He studied 60 patients with mean follow up of 29 months and found early complications (in 40%) which included scrotal swelling, scrotal ecchymosis, urinary urgency and 3% were major (rectal injury and urosepsis). Late complications occurred in 48% which included a feeling of wound tightness, scrotal numbness , urine spraying and only 18% were significant (erectile dysfunction, chordee and fistula).[22]

In a study conducted on 128 patients by Spilotros et al most frequent complications recorded were urinary fistula (n=4; 3.1%), graft contracture (n=4; 3.1%) and graft failure (n=4; 3.1%). Complications were found to occur more commonly in complex stricture of the penile urethra.[23]

6.3 AIMS AND OBJECTIVES OF THE STUDY

- To evaluate the outcome of buccal mucosal graft urethroplasty in patients with anterior urethral stricture.

7.0 MATERIALS AND METHODS

7.1 SOURCE OF DATA:

The data for the study subject will be collected retrospectively and prospectively from 1st August, 2021 to 31st January, 2023 in the Department of Urology, Dayanand Medical College and Hospital, Ludhiana.

7.2 METHOD OF COLLECTION OF DATA

Patients with anterior urethral stricture consenting to participate and fulfilling all the consensus criteria and none of exclusive criteria listed below will be included.

Inclusion Criteria:

1. Strictures > 2.5cm in length
2. Patients requiring repeated internal urethrotomy or dilatations.

Exclusion Criteria:

1. Periurethral phlegmon
2. Multiple urethrocutaneous fistula
3. Associated with chronic renal failure
4. Scarred perineum.

Information shall be collected through a pre-designed performa for each patient chosen to be a part of the study with detailed history, clinical examination and complete investigational workup. A pre-informed consent from each patient shall be taken. Details of the study will be explained to each patient. Analysis will be done with the collected data. Post operatively (one month after surgery) patient will be evaluated by uroflowmetry (peak flow, average flow and voided volume shall be noted) and AUG. Hence preoperative and post operative data will be compared to evaluate the outcome.

The preoperative workup will include careful general physical examination, palpation of the anterior urethra for any mass; glans penis inspection for signs of urethral meatal stenosis or balanitis xerotica obliterans. The perineum will be inspected and examined for the presence of fistulas or periurethral inflammation. Dental surgeon's opinion will be obtained regarding the hygiene of the oral cavity and to rule out any buccal mucosal pathology.

The preoperative variables that will be included in our study are age of the patients, duration, etiology of the stricture disease, preoperative uroflowmetry, history of previous urological intervention, stricture length as per preoperative retrograde urethrogram and intraoperative assessment.

Under nasotracheal intubation, two teams will operate simultaneously in the oral cavity and the perineum. Perineum will be explored with midline perineal incision. Bulbar urethra will be circumferentially mobilized after separating the bulbospongiosus muscle. Strictured urethra and approximately 1 cm of normal urethra will be mobilized proximally and distally. In case of pan urethral stricture penis will be invaginated and the urethra will be separated from the corpus cavernosum up to the meatus. The urethra will be rotated 180 and stricture incised in the 12'0 clock position commencing at the distal end of the stricture and proceeding proximately till you get a healthy urethra admitting 24-26 Fr. bougies without difficulty. At this point, length of stricture and surrounding spongiofibrosis will be assessed. If the dense stricture portion is 1-2 cm with extensive spongiofibrosis proximally or distally, that portion will be excised. The urethral ends will be spatulated dorsally and the ventral ends anastamosed with 4-0 vicryl, forming the floor strip, leaving a diamond shaped defect dorsally. The length of the stricture will be measured.

In the same time the oral surgical team will harvest the buccal mucosal graft. The parotid duct will be identified and desired buccal mucosal graft be outlined and margins infiltrated with sub mucosal injection of 1: 100,000 lignocaine in adrenaline. The graft will be harvested minimizing fat in the undersurface while avoiding dissection into the muscle and going close to the gums. Donor site will be left open. Depending on the length of stricture, buccal mucosal graft will be harvested from one or both cheeks. The graft will be defatted and fenestrated. The graft will be secured to the cavernosa by interrupted vicryl sutures. Quilting sutures will be placed through the graft into the underlying corporal surface along the length of the graft until the entire graft is secured.

The right mucosal margin of the opened urethra will be sutured to the right side of the patch graft, splaying open the strictured tract to new roof, which is spread & fixed to the graft. The urethra will be rotated back to its original position. The left side of the urethra will be sutured to the left side of the patch graft and to the corporal bodies. Bulbospongiosus muscle will be reapproximated. Corrugated drain kept. An indwelling 16 Fr. Foley catheter will be left in place.

In cases with associated meatal stenosis it will be addressed by dorsal on lay buccal mucosal graft with Blandy's type meatoplasty or ventral meatotomy.

The decision of which procedure to perform and length of the buccal mucosal graft needed will partially based on the length and appearance of the stricture on preoperative retrograde urethrography but predominantly on the intraoperative findings of stricture length as well as the appearance of the mucosa and spongy tissue.

Patient will be started on oral fluid on 1st postoperative day and semisolid diet on day 2 and normal diet from third day. The patient will undergo pericatheter study on 21st post operative day and catheter will be kept for one more week if it demonstrates leak. Post operative evaluation (one month after surgery) will be done with uroflowmetry (peak flow, average flow and voided volume shall be noted) and AUG (if needed) and findings will be compared with pre operative values. Relevant pictures will be taken and included in the study.

DURATION OF STUDY – The data for the study subject will be collected retrospectively and prospectively from 1st August, 2021 to 31st January, 2023

OUTCOME: Success will be defined as patient not needing any form of urethral instrumentation. Satisfactory result will be defined as patient who needs urethral manipulation once. Failure will be defined as patient who needs regular urethral dilatation by urologist or revision of urethroplasty or self urethral dilatation.

STATISTICAL ANALYSIS

For discrete data -proportion will be computed and the mean and standard deviation will be computed for the continuous data. The chi

square test will be applied to compare the proportions between the groups to assess the statistical significance. All analyses will be two tailed and p <0.05 will be considered significant. SPSS version 21.0 will be used for data analysis.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

Routine, uroflowmetry, AUG, MCU, ultrasound KUB.

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached here with.

8.0 LIST OF REFERENCES

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PROFORMA

S.No.

Name: Age:

Gender: MRD No.

Address: Adm.No. :

Socioeconomic status:

Presenting complaints:

Duration of stricture:

Etiology:

H/O previous urethral instrumentation:

OIU

Self urethral dilatation urethral dilatation (urologist)

AUG:

Hemogram: Hb TLC

DLC Platelet count

Renal Function Test:

Blood Urea Serum Creatinine

Uroflow:

Date	Uroflowmetry	Peak flow	Avg. flow	Voided vol.

Signature of Candidate **Signature of Supervisor**

Sunit Tandon. Harmandeep

Operative Notes:

Donor site complications:

Urethroplasty complication:

Intervention:

AUG (if needed):

Sumit Tandon.

Signature of Candidate

Signature of Supervisor

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....
.....am willing to participate in the study **"A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

.....
Signature of the patient

Name:

Sunit Tandon.
Signature of Candidate

Signature of Supervisor

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____

गवाह के हस्ताक्षर

नाम:

_____

रोगी के हस्ताक्षर/अंगूठे का निशान

नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"A STUDY TO EVALUATE THE OUTCOME OF BUCCAL MUCOSAL GRAFT URETHROPLASTY IN ANTERIOR URETHRAL STRICTURE" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ